VILLA SISTEMI MEDICALI

Arcovis 3000

Revision: G
Version: May 26, 2010
File: [201175-F-01-01.doc]

User's Manual

WARNING: The information that is printed within this manual is vital for the correct use of the equipment; please read it carefully before use.

This page is intentionally left blank

Table of contents

1. SAFETY AND COMPLIANCE 2
1.1. Electrical safety 3
1.2. Laser targeting devices safety 3
1.3. Mechanical safety 3
1.4. Electromagnetic compatibility (EMC) 4
1.5. Protection against ionizing radiation 4
1.6. General disposal 5
1.7. Interfaceability 5
1.8. Copyright 5
1.9. Application and final destination 6
1.10. Classification 7
1.11. List of the Standards for the evaluation of the product compliance 7
1.12. Compliance 7
2. COMPONENT IDENTIFICATION 8
2.1. Overview 8
2.2. Mobile Stand 10
2.3. Keyboard 12
2.4. Fluoroscopy control footswitch 18
2.5. Handswitch for radiography / fluoroscopy control 18
2.6. Monitor Trolley 19
2.7. Operative messages 20
2.8. Alarm messages 21
2.9. Safety devices 23
3. UNIT USE 24
3.1. Transport 24
3.2. Connection between monitor trolley – mobile stand 25
3.3. Connection between Footswitch – Mobile Stand 26
3.4. Unit ON / OFF 27
3.5. Positioning 29
3.6. Use mode 30
3.7. Shutdown procedure 40
4. MAINTENANCE 41
4.1. General warnings 41
4.2. Checks and inspection by the user 41
4.3. Cleaning 42
4.4. Disinfection 42
5. TECHNICAL DATA 43
5.1. Labels and symbols 43
5.2. Environmental conditions 47
5.3. Electrical data 48
5.4. Exposure mode: fluoroscopy 58
5.5. Exposure mode: radiography 61
5.6. Image system 62
5.7. Digital image processor 65
5.8. Accessories 70
6. MECHANICAL DATA 73
6.1. C-arm unit dimensions with I.I. 9” 73
6.2. Axis and interventionist reference point 73
6.3. “Base Trolley” monitor trolley dimensions 74
6.4. Dimensions of “High Configuration” monitor trolley 75
6.5. Mechanical data, dimensions and weights 76
7. DOCUMENT STATUS I

1. SAFETY AND COMPLIANCE

The purpose of this user's manual is to provide a set of easy to use instructions for the proper use of the system. All of the information contained herein is based on the current version of the system. Villa Sistemi Medicali reserves the right to improve and implement changes to the information herein to reflect any changes necessitated by technological enhancements to the system.

This x-ray unit must be used in strict compliance with the safety instructions contained in this manual and must not be used for purposes other those for which it was intended.

The x-ray unit may only be operated by skilled, properly trained personnel with the required knowledge of x-ray safety practices and the proper use of x-ray equipment.
The operator is responsible for the use of the system in compliance with the applicable standards concerning installation and use.

The system safety circuits and devices must not, for any reason, be moved, modified, or omitted.
The monitor trolley key switch may only be activated by authorized personnel and only during the use of the system. Once system use has been completed, the key must be removed and stored in a safe place.

The unit must not be operated when electrical, mechanical, or radiological faults are present or when any of the indicators or alarm devices are malfunctioning.

When used in conjunction with other apparatus, components, or modules, whose compatibility is uncertain, it is necessary to ensure the absence of any danger to the patient or operator. Consult Villa Sistemi Medicali for information.

As with any technical apparatus, this x-ray unit must be used properly with periodic checks and maintenance as specified in the chapter “Planned maintenance” of the Service Manual.

Villa Sistemi Medicali is responsible for the safety of its products only when maintenance, repairs, or modifications have been performed by its personnel or by personnel authorized by Villa Sistemi Medicali in writing.

Villa Sistemi Medicali cannot be held liable for any malfunction, damage, or danger resulting from improper use of the system or non-compliance with the rules for proper maintenance.

1.1. Electrical safety

Only trained service personnel authorized by Villa Sistemi Medicali may remove the unit covers and only in accordance with the instructions contained in the Service Manual.

This x-ray unit may only be used in environments or medical rooms in compliance with the applicable IEC standards.
The x-ray unit must not be used in areas where there exists a danger of explosion.
Cleaning and disinfecting agents, including those used on patients, may create an explosive, gaseous mixture. Use only those products in compliance with the applicable rules.

1.2. Laser targeting devices safety

- Keep always a good lightening on the room.
- Never look through the output window of the laser targeting device.
- Never fix the reflections of the laser targeting devices.
- Before starting any examination, the patient must remove earrings, glasses, necklaces and whatever could reflect the laser beam and be printed on the image.
- Don't clean the openings of the laser targeting devices with tools that could modify their optics. Only the service personnel must perform possible cleaning actions.
- The min. distance between the laser source and the patient must not be lower than cm20.

The only purpose of the laser use is to reduce the patient dose to a minimum, it doesn't be considered as an absolute means of centering.
The activation of procedures other those listed above can cause the emission of dangerous non-ionizing radiations.

1.3. Mechanical safety

The unit can be moved only by trained personnel by complying with the following safety conditions:

- Move the unit by considering the conditions for the movement that are indicated in detail in the paragraph 3.1.
- Don't move and use the unit on surfaces with inclination higher than 5°
- Only use the proper handles to move the unit.
- Avoid collision with obstacles.
- After positioning the unit, engage the parking brakes.

1.4. Electromagnetic compatibility (EMC)

This apparatus is in compliance with the standard IEC 60601-1-2 that defines the max. allowed emission levels from electronic devices and the required immunity from interference caused by externally generated electromagnetic fields.

It is not, however, possible to exclude radio signals coming from transmitters such as mobile phones or similar mobile radio devices. These and other transmitting devices, including those in compliance with the EMC standards, may influence the proper functioning of medical apparatus when used in proximity and with a relatively high transmitting power. Therefore, the use of radio equipment proximity to electronically controlled systems must be avoided in order to eliminate any interference risk.

Any transmissions by mobile radio equipment must be avoided.
Mobile phones must be switched off in zones close to the unit.
These rules must be applied when the unit is switched on (that is to say connected to the mains and ready for use).

1.5. Protection against ionizing radiation

Before any x-ray exposure, ensure that all the necessary protective precautions have been taken.

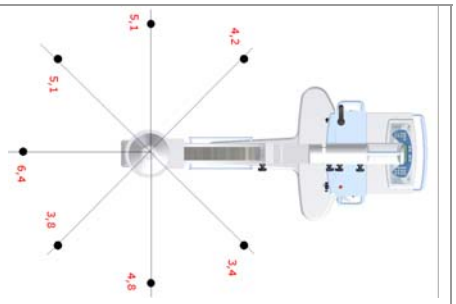
During the use of x-rays, personnel present in the room must comply with the following rules concerning protection against ionizing radiation:

When necessary, use protective shielding against radiation in addition to the shielding already provided on the unit.
Use protective aprons containing a material equivalent to 0,35mm of lead. Material of this nature reduces radiation at 50kV by 99,95% and at 100kV by 94,5%.
The best protection against radiation is distance. It is therefore recommended that you stay as far as possible from the x-ray source and the exposure target. For this purpose, use all of the cable length provided for the foot-switch.
Avoid walking or standing directly in the x-ray beam.
Always use the smallest possible field of exposure by closing properly the collimator diaphragms. The scatter dose produced depends principally on the volume of the irradiated object.

Never modify or disconnect the safety circuits or devices designed to prevent accidental exposures.

Collimation system adjusted to a field of 30 x 30 cm2 at 1 m from the x-ray tube focus.
Exposure parameters: 100 kVp and 1 mA.
Values normalized to 1 min. of fluoroscopy (µGy/min).
Equivalent water phantom 30x30x20cm.

The complete isodose measures are included into the report 035-07 ISO KERMA MAPPING (cod.200394) attached to the unit documentation



1.6. General disposal

Villa Sistemi Medicali produces radiological systems that are advanced in terms of safety and environmental protection. Assuming that the unit is properly used, there is no risk to people or the environment.
In order to comply with applicable safety requirements, it is necessary to use materials that may be harmful to the environment (for example: monobloc oil, protective lead, monitor kinescope, boards and electronic components). Therefore, when necessary, proper disposal methods, according to the regulations of the country where the unit is installed, should be followed.

For this reason, the unit may not be disposed of along with industrial or domestic waste and must be regarded as hazardous waste.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.
The proper differentiated collection for the following start of the unit disused to the recycle, treatment and disposal, compatible with the environment, aid to prevent possible negative effects on the environment and health and it favours the recycle of materials that compose the unit.
The abusive disposal of the product from the user implies the application of administrative sanctions according to the Standards in force of the unit installation country.
For information concerning the dismantling modes of the units out of use, stick to the local provisions or contact a representative authorized by the manufacturer.

For additional information, contact Villa Sistemi Medicali.

1.7. Interfaceability

The device does not forecast any interaction with devices for medication.
It is possible to interface the unit with certain devices such as DVD Recorder, thermal printer, Network (DICOM System). Such devices must be in full compliance with the safety requirements specified by 93/42/EEC Directive. The liability of the interface, if it has not been evaluated and authorized by Villa Sistemi Medicali in writing, is of the operator and/or of the person who has performed this interface.

1.8. Copyright

The original release of this manual is in Italian language (file: 201175-C-01-00.doc). For further information, please refer to the Italian version.
The software contained in the unit belongs to Technix S.p.A.. Upon receipt of the unit, the user acquires the right to use the software. **This right is neither exclusive nor transferable.**
Written authorization to Technix S.p.A. is mandatory prior to any modifications for the unit use with functions other than the ones foreseen.

1.9. Application and final destination

ARCOVIS 3000 S/R is a "mobile x-ray unit with image intensifier system" and it has been designed to be used for diagnosis. It must be operated exclusively by qualified, trained personnel who have been informed of the risks linked to the use of ionizing radiation.

The system does not belong to the category of equipment designed for continuous operation.

The system is not used in contact with the patient; however, accidental contact of some unit parts with the patient and the operator is possible.

Contact with the patient is non-invasive.

Contact with the operator is strictly for reasons linked to the use of the equipment (normal operation).

The unit is suitable to be used for x-ray examinations, and in particular for radioscopy, radiography and diagnosis dedicated to:

- Traumatology
- Pediatrics
- Simple interventional radiology
- Pace Maker implantation
- Operating theater
- Intensive care
- Respiratory system
- Skeletal structure

This x-ray unit must not be used in areas where danger of explosion exists.
For use in operating theater, it is necessary to use a sterile coverings to protect the arm-monobloc-intensifier group from liquids seepage and a footswitch type IP-X8 (like the standard one).

The patient support *must* not have an equivalent filtration higher than 2mmAl.
The patient *must* be placed as close as possible to the image intensifier.

The unit is available in two versions:
ARCOVIS 3000 S with stationary anode monobloc, successively named "Stationary anode version",
ARCOVIS 3000 R with rotating anode monobloc, successively named "Rotating anode version".
If not else specified, the technical characteristics are intended available for both versions.

1.10. Classification

Protection against electrical hazards ..... Class I
Protection against direct and indirect contact Unit Type B with Type B applied part
Protection against water penetration..... Common protection (IPXO)
Fluoroscopy footswitch protected against the submersion effects (IPX8)
Use condition protection..... Continuous working with temporary load

1.11. List of the Standards for the evaluation of the product compliance

Reference	Description
MDD 93/42/EEC class IIB according to Annex IX rule 10.	Medical Devices Directive (EC mark)
IEC 60601-1 1st edition	Medical devices safety
IEC 60601-1-2 1st edition	Electromagnetic compatibility
IEC 60601-1-3 1st edition	Protection against ionizing radiation
IEC 60601-2-7 2nd edition	HV generators
IEC 60601-2-28 1st edition	Tube-housing groups
IEC 60601-2-32 1st edition	Mechanical safety aspects
ISO 14971:2000	Risk analysis
CEI EN 60825-1 2nd edition	Laser equipment safety

ARCOVIS 3000 S/R with radio-protection according to the Standard CEI EN 60601-1-3 (1995)

Gruppo Inverter-monoblocco: (IN-9040-5 HF + I-40S 3,5 RF, IN-9040-5 HF + I-40R 5 RF) EN60601-2-7:1998

X-ray group for diagnostics ARCOVIS 3000 S/R IEC 601-2-28 (1993)

Complementary unit ARCOVIS 3000 S/R IEC 601-2-32

1.12. Compliance

CE 0051

This x-ray unit is in compliance with the Electromedical Devices Directive 93/42 EEC class IIb and with the Annex IX rule 10.

For any further information concerning the compliance please contact:

Villa Sistemi Medicali
Via delle Azalee, 3
20090 Buccinasco, MI (ITALY)
Tel: +39-02-48.859.1
Fax: +39-02-48.81.844
E-mail: vsmservice@villasm.com

The manufacturer (according to the European Directive 93/42/EEC) of the unit ARCOVIS 3000 S/R is:

Technix S.p.A.
Via E. Fermi, 45
24050 Grassobbio, BG (ITALY)
Tel: +39 (0)35-3846611
Fax: +39 (0)35-335675

2. COMPONENT IDENTIFICATION

2.1. Overview

The unit ARCOVIS 3000 S/R is made up of two different parts: Mobile Stand and Display Station.

Mobile stand consisting of:
"C" Arm, Monobloc, Image Intensifier, Control Panel (Fig. 1).

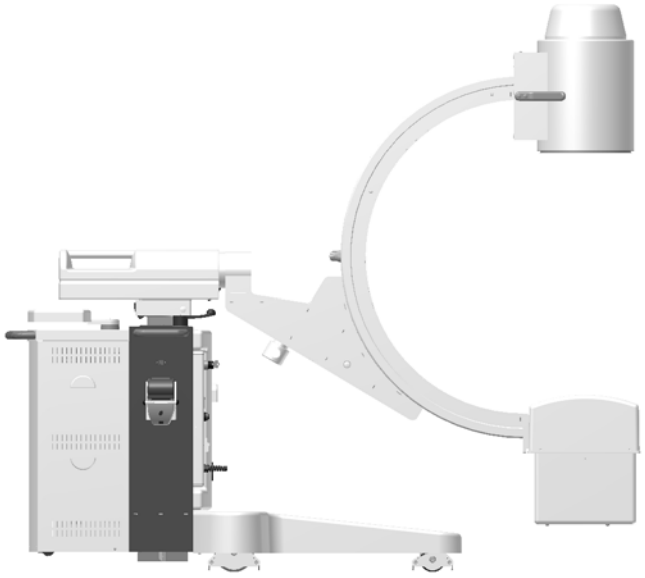


Fig. 1

Display Station consisting of:

- nr.1 orientable LCD monitor 17", directly on mobile stand for digital systems with CCD 0,5K x 0,5K (Fig. 2). *
- "Low Profile Base Trolley" with two LCD monitors 19" for video systems 0,5K^2 (Fig. 3).
- "High Profile Base Trolley" with two monitors 18" for video systems 1K^2 (Fig. 4).
- "High Configuration" trolley with two monitors 19"/18" for video systems 0,5K^2 / 1k^2 (Fig. 5).

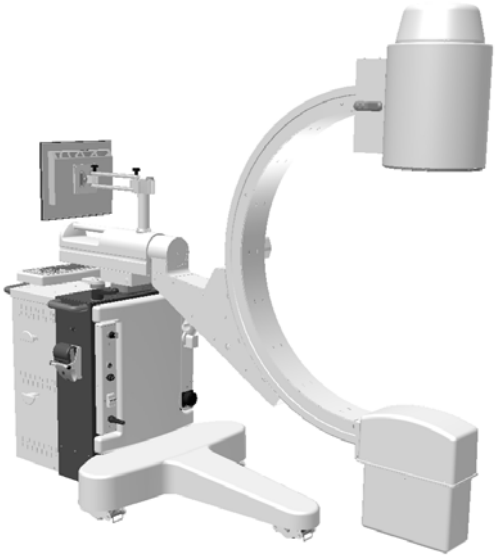


Fig. 2

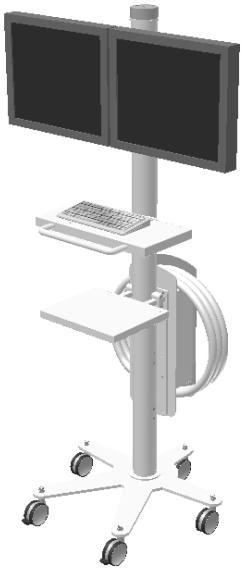


Fig. 3

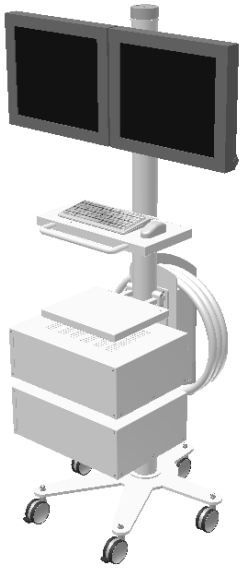


Fig. 4

Fig. 5

** Note: the number of the monitors and the monitor trolley change according to the image system choice.*

2.2. Mobile Stand

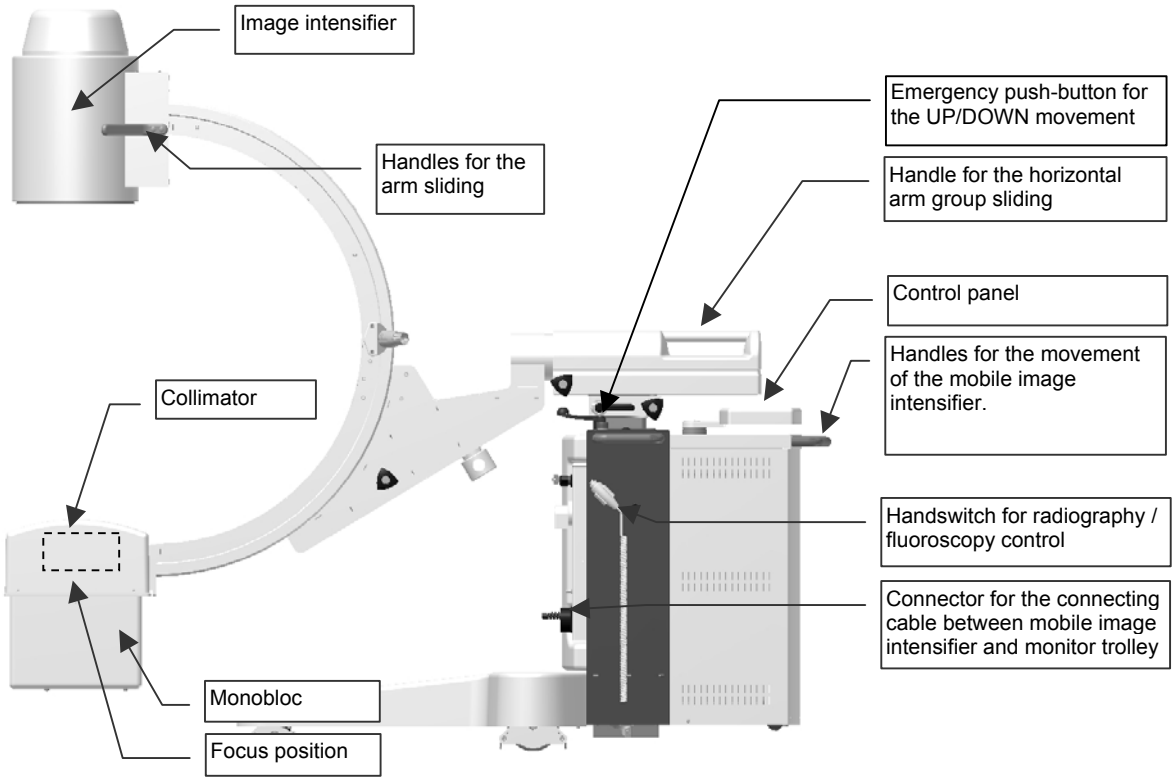


Fig. 6

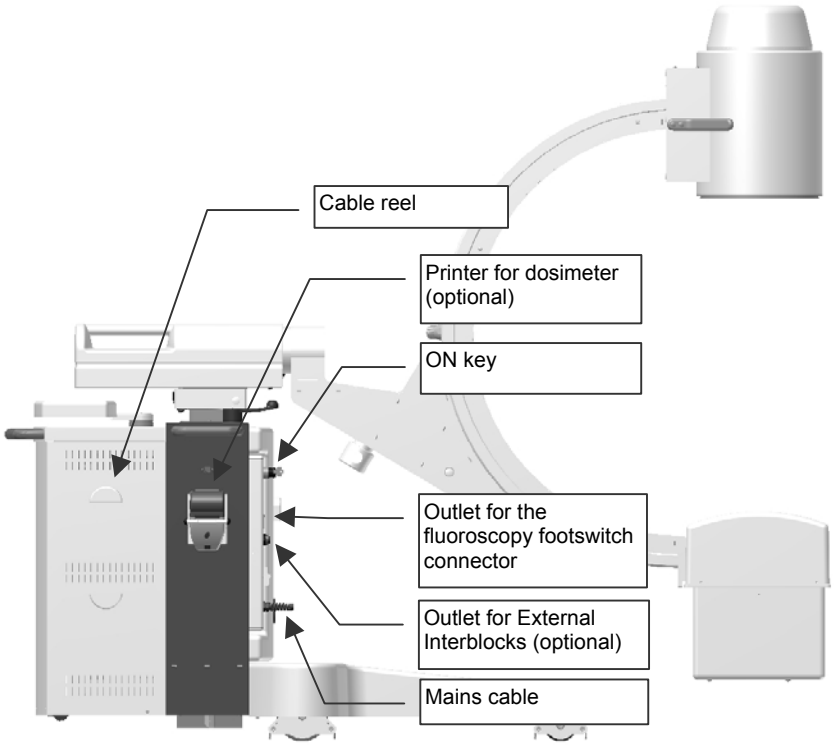


Fig. 7

2.2.1. Handles and brakes position for manual movements

The brake handle is take-up type. In order to avoid collision dangers with the unit or the user, always put the handle again in horizontal position.

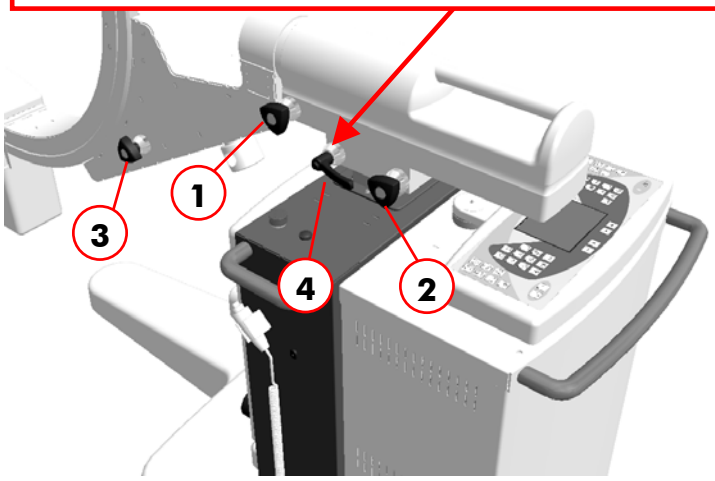
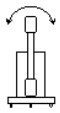
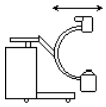


Fig. 8

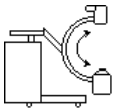
1. Brake for the arm rotation around the horizontal axis. Movement:±270°



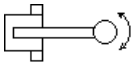
2. Brake for horizontal sliding of the arm group. Movement: 220mm



3. Brake for the orbital arm rotation. Movement:123° (+90°÷-33°)



4. Brake for the overview movement of the arm group. Movement: ±12,5°



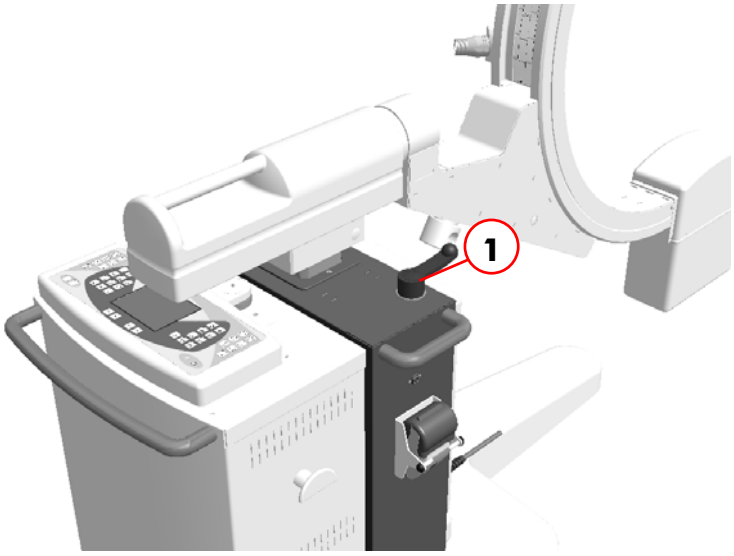
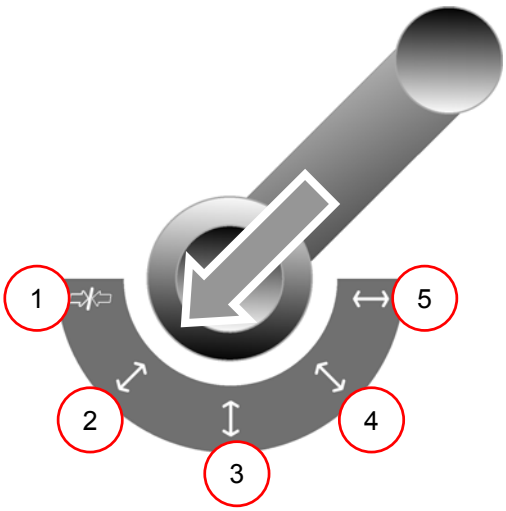


Fig. 9

1. Driving handle and rear wheels braking



Pos.1: brake ON

Pos.2: oblique movement

Pos.3: free movement

Pos. 4: oblique movement

Pos.5: right-left movement

2.3. Keyboard

2.3.1. Unit

All keys are membrane type. The keyboard group can rotate ±45° in respect of the central position for its simpler use.

Fig. 10

Area 1

Vertical arm movement		Laser targeting device OFF/ON	
System OFF		Led for x-ray emission signal	
System ON		Alarm signal	

Area 2

Digital image rotation [1]		Shutters diaphragm rotation	
Image enlargement		Shutters diaphragm closing/opening	
Horizontal image reversal		Iris diaphragm closing/opening	
Image edges enhancement		ENTER	ENTER + F1: “Utility Mode” selection
Motion Detector (unavailable function)		F1	
Stored images scrolling		F2	Commutation between LIVE image and MEM image on single monitor.
Image transfer from the live monitor to the memory monitor			
kV decrease / increase		mA/mAs decrease / increase	

[1] For SBFM78, DIP and HRC memories series: by pressing at the same time the two rotation push-buttons for four seconds, there is the digital image rotation resetting.

2.3.2. "Base Monitor Trolley"

Memories series SBFM /HRC

The memory series SBFM76 has not the keyboard.
The memories series SBFM78 have only the alphanumeric keyboard for the patient data input.

F1	allows PATIENT NAME (max 63 characters) to be inserted
F10	allows DATE and TIME to be inserted
F5	allows activation of NEGATIVE function on Memory Monitor
HOME	shows last image recently memorized
END	shows last image in the memory buffer
PG UP	scan of memorized images in increasing order
PG DN	scan of memorized images in decreasing order

The SBFM device is equipped with the possibility of completely clearing all memorized images.
To use this function, press "PG UP" and "PG DN" commands at the same time for approximately 4 seconds (clearing time: from 10 sec to 2 min)

The keyboard can be placed under the unit keyboard (unit with monitor aboard) or on the highest shelf of the "Base Trolley" in "Low Profile" configuration.
The memories series HRC have the alphanumeric keyboard and mouse for the patient data input. Keyboard and mouse are placed on the highest shelf of the "Base Trolley" in "High Profile" configuration.

2.3.3. High Configuration trolley

On the High Configuration trolleys, there is always a small remote keyboard that duplicates some controls present on the unit keyboard.
All keys are membrane type.

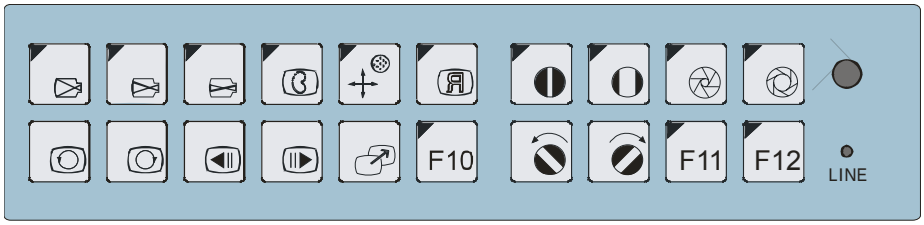
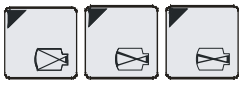
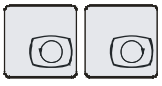
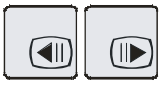
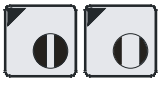
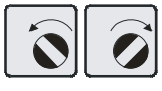
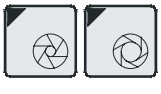


Fig. 11

1^ line		2^ line	
	Image enlargement		Digital image rotation
	Image edges enhancement		Stored images scrolling
	Motion Detector (unavailable function)		Image transfer from the live monitor to the memory monitor
	Image reversal on vertical axis		n.u.
	Shutters diaphragm closing/opening		Shutters diaphragm rotation
	Iris diaphragm closing/opening		n.u.

Memories series DIP

The memories series DIP have a keyboard dedicated to the post processing.
All keys are membrane type.

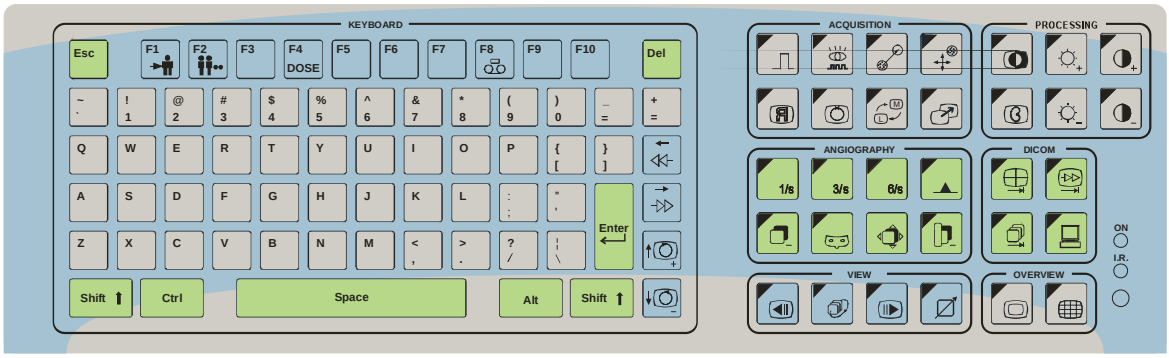


Fig. 12

For an easier understanding they have been divided into 7 different groups: KEYBOARD, ACQUISITION, PROCESSING, ANGIOGRAPHY, DICOM, VIEW, OVERVIEW

KEYBOARD

F1	New exam	F2	Patients list
F4 DOSE	Dose information	F8	VCR prearrangement
	Search start backwards		Search start onwards
	Rotation +		Rotation -

ACQUISITION

	SNAPSHOT control prearrangement		Image reversal on vertical axis
	PULSED FLUOROSCOPY control prearrangement		Image rotation resetting
	Recursive filter selection		MEM image and FLUOROSCOPY alternation
	SMART filter activation / deactivation		Image storage key

PROCESSING

It allows the images visualization in negative

SHARP / SMOOTH / OFF edges processing

Key to increase the brightness

Key to increase the contrast

Key to decrease the brightness

Key to decrease the contrast

ANGIOGRAPHY

Angiographic acquisition rate selection 1 image per second

Key for the mode activation of the subtraction between images

Angiographic acquisition rate selection 3 images per second

Mask acquisition key

Angiographic acquisition rate selection 6 images per second

SHIFTING PIXEL function activation

MAX OP control activation / deactivation

LAND MARK control activation

DICOM

Single image sending to DTU

Whole exam sending to DTU

Current RUN sending to DTU

DTU monitor commutation

VIEW

Memory number decrease

Memory number increase

ALTERNATE MEMORY procedure control

Key to delete the images stored in the buffer (active only in DISKLESS mode)

OVERVIEW

Stored image zoom

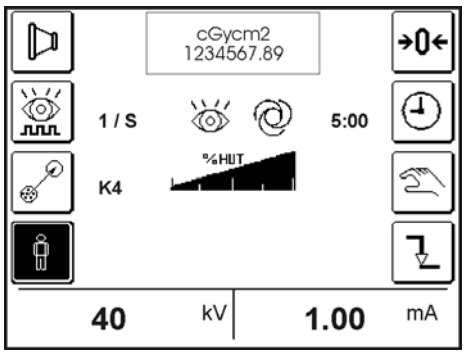
Stored images overview

Memories series HRP

The memories series HRP have the alphanumeric keyboard and the mouse for the patient data input.
All keys are membrane type.

2.3.4. Display

Alphanumeric touch-screen display 5” for x-ray parameters and warning/error messages.



The keys, so-called at “retention”, are displayed:

in positive on white background for the non-active function

in negative on black background for the active function

Note: the box with the dose indication is displayed only if the dosimeter is installed and in working condition.

2.3.5. Audible signals

1 BEEP[2]	Sound signal when any key is pressed.
2 BEEPS	Storage OK.
A LONG BEEP (about 1sec)	Alarm, malfunction.

[2] *It is possible to deactivate the audible signals or modify the volume (§3.6.10* Utility Mode*).*

2.4. *Fluoroscopy control footswitch*

The footswitch is enabled only in fluoroscopy mode.

The fluoroscopy control footswitch consists of a double-step pedal and two single-step ones. The functions in the different modes are:

1. **Left pedal (two steps):**

   Fluoroscopy Mode:
   1° step: **fluoroscopy control**.
   2° step: **image storage**; in continuous fluoroscopy the current image is stored.

2. **Right pedal (a step):**

   Pulsed fluoroscopy mode.

3. **Third pedal (a step):**

   Fluoroscopy mode:
   "snapshot" control (high-contrast exposure with reduced background noise).

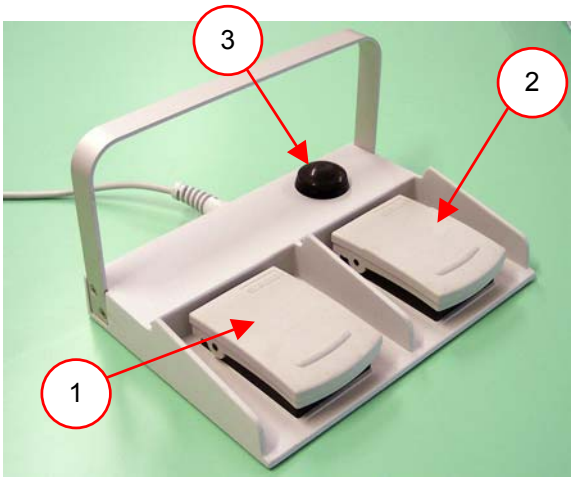


Fig. 13

2.5. *Handswitch for radiography / fluoroscopy control*

The control handswitch is made of a two-steps switch.

Radiography mode:
1° step: **preparation control**.
2° step: **emission control**.
In radiography mode it is possible to press immediately the exposure control (2° step), with an emission delay due to the anode starting phase *(only for rotating anode version)*.

It is possible to control Fluoroscopy and Storage even with the radiography handswitch.
Fluoroscopy mode:
1° step: **fluoroscopy control**.
2° step: **image storage**.

Normally the function is enabled. In order to disable it, it is necessary Service intervention.

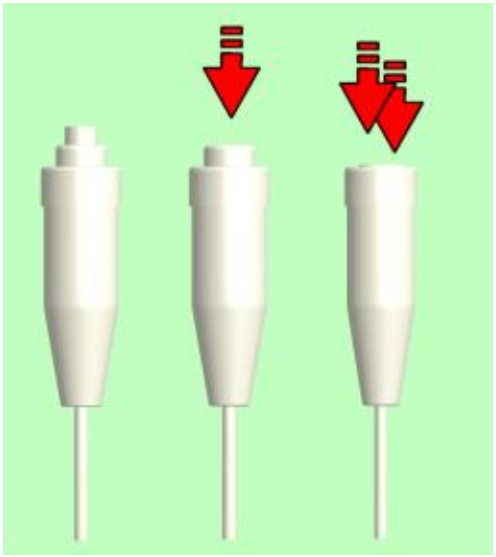
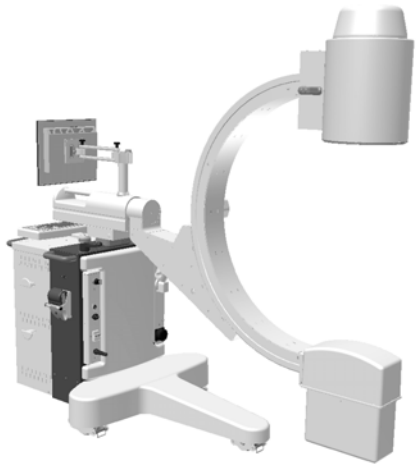
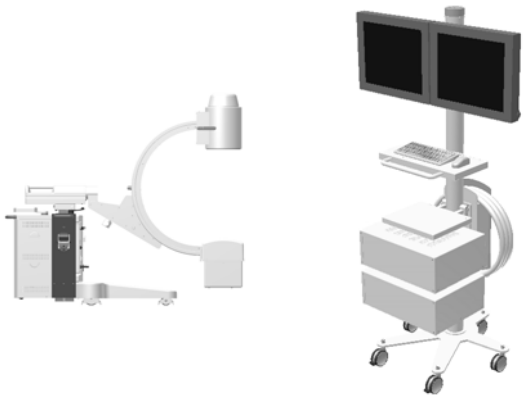
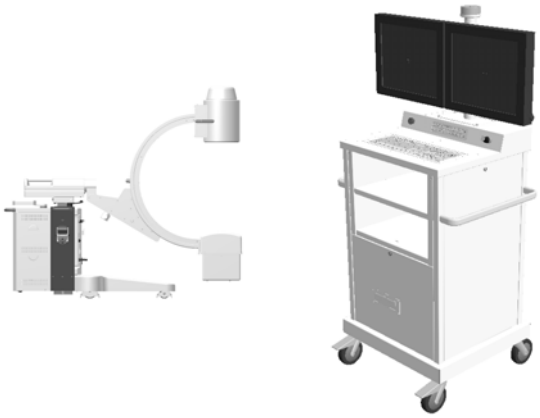


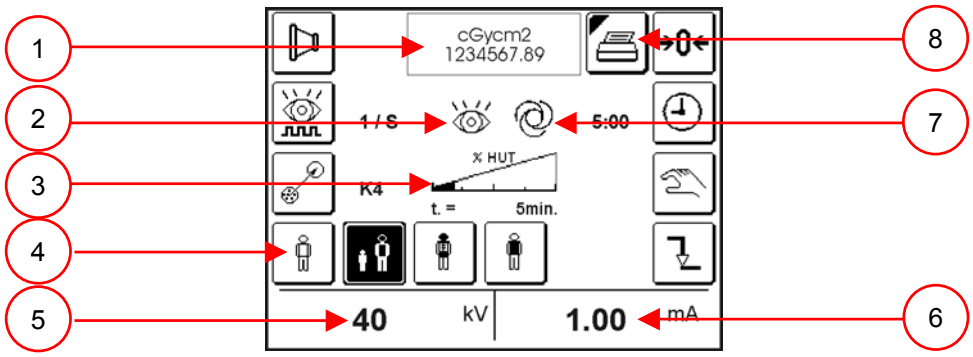
Fig. 14

2.6. Monitor Trolley

 Unit “ARCOVIS 3000 S/R” with monitor aboard	Unit “ARCOVIS 3000 S/R” + “Low Profile Base Trolley”
 Unit “ARCOVIS 3000 S/R” + “High Profile Base Trolley”	 Unit “ARCOVIS 3000 S/R” + “High Configuration” trolley

2.7. *Operative messages*

Display in fluoroscopy mode



1 Indication of the dose value (only if the dosimeter is present and in working condition / MESSAGES and/or ERRORS Area)

2 Indication of the FLUOROSCOPY / RADIOGRAPHY phase.

3 Indication of the available thermal units (HUT), expressed in percentage from 0% (indicator completely white and spent HUT) to 100% (indicator completely black and available HUT).

When the residual HUT value allows a use of the unit below five minutes, under the indicator will appear also the residual time indication (t = …min), valued in function of the employed power. Simultaneously it's issued an acoustic alarm not modifiable.

When the residual HUT reach 0%, the x-rays emission block intervenes.

It's possible to exceed this limit and proceed with the x-rays emission (only in fluoroscopy mode) till intervention of monobloc thermal security.

This choice must be performed by Service personnel and on express request of the final user.

As the monobloc temperature decreases, the HUT will be regenerated. Residual time indication will disappear, when thermal units allow a use exceeding five minutes.

4 Selection of the Anatomic Curve in Fluoroscopy (Standard / Paediatric / Pelvis-Head / Standard for sturdy patient (*only for rotating anode with camera 1K*^{2})).

5 Indication of the set kV value. It changes in Automatic mode or in Manual mode by using the kV+ and kV- keys of the control panel.

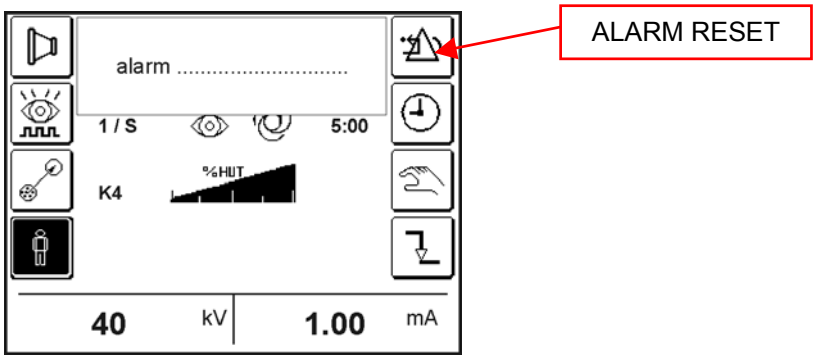
6 Indication of mA value concerning kV and the selected curve. During the exposure it indicates the measured mA value.

7 Indication of the AUTOMATIC / MANUAL mode.

8 Dose printing key. It appears if the dosimeter is present and in working condition and if the printing mode in Utility Mode is selected (§3.6.10).

2.8. *Alarm messages*

In case of alarm condition, the alarm messages are displayed in an appropriate box with audio-visible signals.
The key for the dose visualization resetting changes in ALARM RESET.
When an error/warning appears, press the key “ALARM RESET” to reset the audible signal, delete the message and go on to work.



The table indicates how to proceed in case of faults and anomalies.

Text	Meaning	Intervention
DOSIMETER NOT OK	The dosimeter does not reply.	Press the “ALARM RESET” key in order to go on to work. Check that it is not selected when it is not present on the unit. Call Service to perform the necessary checks.
MAINTENANCE REQUIRED	At least eleven months are passed from the last performed planned maintenance.	Press the “ALARM RESET” key in order to go on to work. Call Service to perform the planned maintenance.
REAL TIME CLOCK ERROR	The system clock does not work.	Press the “ALARM RESET” key in order to go on to work. Warning! This function results particularly important for the calculation of the thermal units recovery. Call Service to perform the necessary checks.
EXHAUSTED THERMAL UNIT	The thermal capacity of the monobloc is exhausted.	Wait for the thermal units recovery.
EXHAUSTED XR TIME	Continuous fluoroscopy time exhausted (max 10min)	Release the footswitch and go on with the operation.
GENERATOR OFFLINE	The generator does not communicate with the central unit.	Switch the unit OFF, wait for some seconds and switch ON again. In case the error persists, call Service.
CAN-BUS ERROR	Error in the field bus	Switch the unit OFF, wait for some seconds and switch ON again. In case the error persists, call Service.
MEMORY CONTROLLER OFFLINE	The memory does not communicate with the central unit.	Switch the unit OFF, wait for some seconds and switch ON again. In case the error persists, call Service.

MOTOR DRIVER COMMUNICATION * *** Iris – Rotation – Shutters**	The collimator motor does not communicate with the central unit.	Press the "ALARM RESET" key in order to go on to work (it is possible to go on with XR, if the I.I. field results to be free). In case the error persists, call Service.
FILAMENT ERROR	Problems found in the filament management.	Press the "ALARM RESET" key in order to go on to work. If the error repeats and persists also at the next start-up, call Service.
KV ERROR	Error in the kV generation	Press the "ALARM RESET" key in order to go on to work. If the error repeats and persists also at the next start-up, call Service.
mA OVERLOAD	Error in the mA reading (over the max. allowed limit)	Press the "ALARM RESET" key in order to go on to work. If the error repeats and persists also at the next start-up, call Service.
THERMIC ALARM	The temperature of the monobloc has reached the max. allowed value.	Wait for the tube cooling
EMERGENCY UP/DOWN PUSHED	Pressed UP/DOWN emergency push-button.	Reset the correct working of the emergency push-button by turning it clockwise.
POWER SUPPLY ERROR	Incorrect secondary power supply	Switch the unit OFF, wait for some seconds and switch ON again. In case the error persists, call Service.
FOOTSWITCH OR HANDSWITCH ERROR	Faulty or damaged footswitch or handswitch for the x-ray control	Disconnect and reconnect the footswitch. In case the error persists, call Service.
STARTER FAULT Only rotating anode	Error in the circuit of the rotating anode.	Switch the unit OFF, wait for some seconds and switch ON again. In case the error persists, call Service.
OPEN DOOR WARNING	For the units provided with the door control, the door to enter the room is open.	Check that the door is closed correctly. In case the error persists, call Service.
VIDEO SIGNAL NOT OK	The video signal is not present or it is not bright enough.	Switch the unit OFF, wait for some seconds and switch ON again. Check that the trolley is connected to the unit and that the BNC cables are properly connected to the monitors. In case the error persists, call Service.
UNAVAILABLE INVERTER POWER SUPPLY	Unavailable inverter power supply	Switch the unit OFF, wait for some seconds and switch ON again. In case the error persists, call Service.
MAX. X-RAY TIME	The max. exposure time has been reached.	Press "ALARM RESET" key to go on, repeat x-rays. In case the error persists, call Service.
TIMEOUT	The preparation handswitch is held down for more than 15 seconds without performing x-rays.	Release the preparation handswitch and repeat the operation.
MANUAL X-RAY STOP	The x-ray hand switch has been released before the end of the exposure.	Press "ALARM RESET" key to go on and repeat the exposure.
MISSING PULSES	Control pulses lack from the memory	Press the "ALARM RESET" key in order to go on to work. In case the error persists, call Service.
CCA BUSY	Busy central unit control	Press the "ALARM RESET" key in order to go on to work. In case the error persists, call Service.

2.9. Safety devices

ARCOVIS 3000 S/R is protected against short circuits through a magneto-thermic switch placed on the unit (pos. 1).
In case the magneto-thermic switch intervenes, in order to reactivate the working of the unit, place the magneto-thermic switch control in “ON” condition.
Furthermore, the unit has got a mushroom emergency push-button placed on the console (pos. 2). It allows to stop the UP-DOWN arm movement in case of danger.
In order to restore the UP-DOWN movement, rotate clockwise the push-button body.

A removable operating key (pos. 3), that is necessary for the unit setup, prevents the unit use from non-authorized personnel.

In case of “High Configuration” trolley, the magneto-thermic switch (pos. 1) and the safety key (pos. 3) are not on the unit but on the trolley. Furthermore, on the “High Configuration” trolley there is a mushroom-head emergency push-button that stops the power supply to the whole unit (pos. 4).

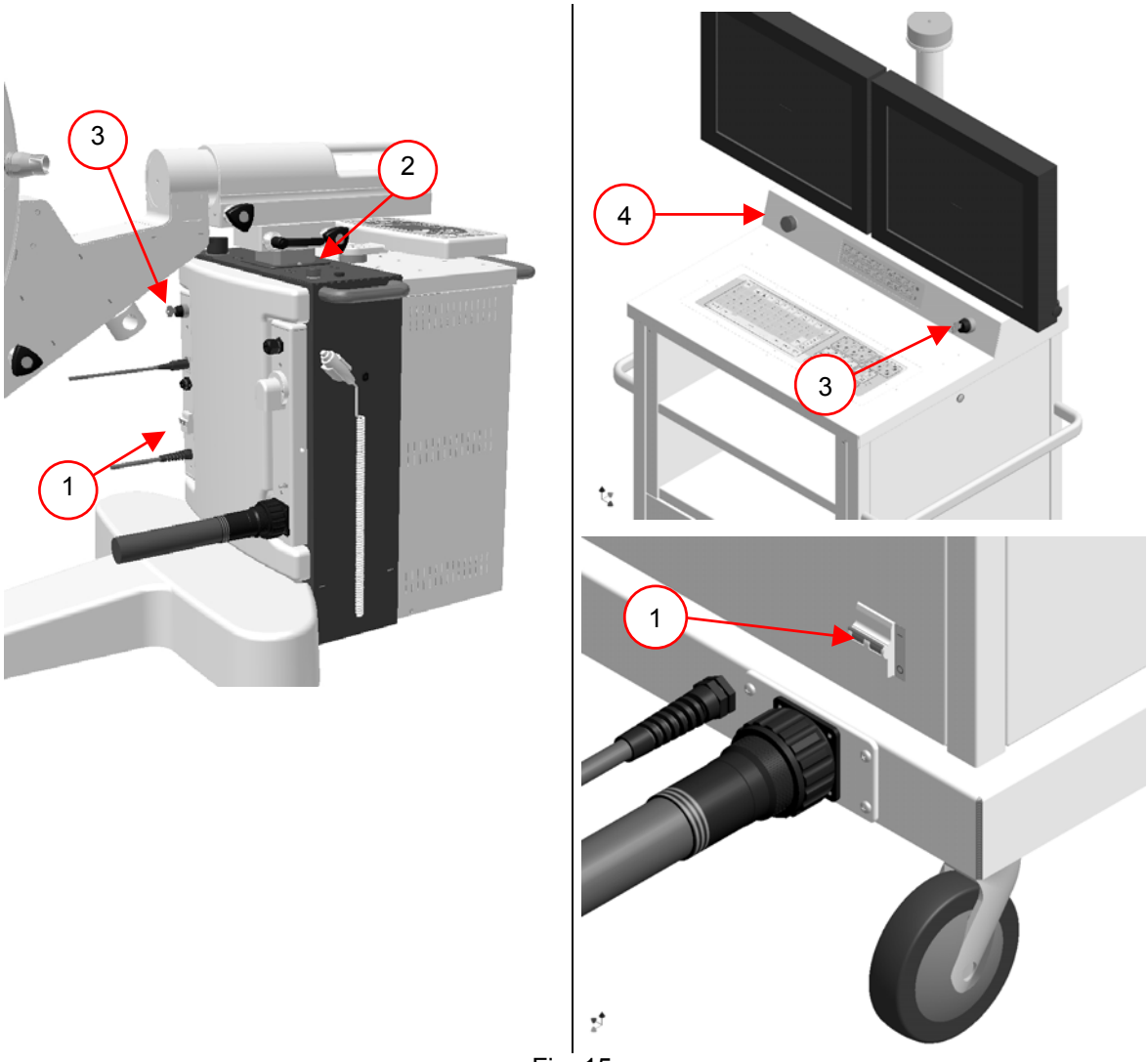


Fig. 15

3. UNIT USE

3.1. Transport

DON'T MOVE THE UNIT ON PLANES WITH INCLINATION HIGHER THAN 5°.
THE UNIT MUST BE MOVED ONLY IN THE CONDITION DEFINED "OF TRANSPORT" (FIG. 16) AND WITH ALL THE ARM MOVEMENT BRAKES ON.
THE UNCONTROLLED ARM MOVEMENT COULD CAUSE DAMAGES TO THE OPERATOR, PATIENT AND PERSONNEL THAT ARE NEAR THE UNIT.

BEFORE MOVING THE UNIT, ENSURE THAT IT IS IN SAFETY POSITION AS SHOWN IN FIG. 16:
THE SEQUENCE DESCRIBED BELOW SHOWS HOW TO PUT THE UNIT IN SAFETY POSITION:

1. OVERVIEW POSITION AT 0°

2. ARM ROTATION AT 0°

3. HORIZONTAL POSITION OF THE ARM GROUP. IT IS ALL BACK.

4. ORBITAL POSITION OF THE ARM AT 0°.

5. VERTICAL POSITION OF THE ARM GROUP. IT IS ALL DOWN.

6. ALL THE SAFETY SYSTEMS AND THE BRAKES ON. (CFR.§2.2.1).

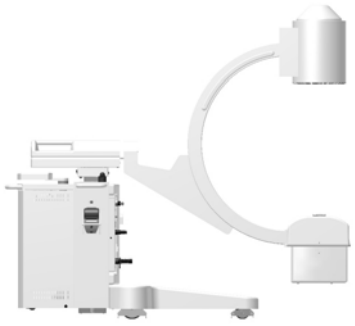


Fig. 16

The unit must be OFF, the mains plug removed from the outlet and the cable winded-up on the cable reel.
The monitor trolley must be disconnected from the Mobile Stand and the cables winded around the reel.

- check that the arm movement brakes are all ON (locked) (see Fig. 8).
- **don't move the unit on planes with inclination higher than 5°.**
- **move the unit only after unlocking the parking brake and use only the proper handles (see Fig. 9 pos.3).**
- in order to make the movement easier, use the rotation of the rear wheels of the mobile image intensifier.

3.2. *Connection between monitor trolley – mobile stand*

Only for version with monitor trolley

The connection between these parts of ARCOVIS 3000 S/R is performed through a multipolar connector with bayonet connection.
On “Base Trolleys”, the cable is fixed permanently from the monitor trolley side, whilst it is sectionable from the unit side.
On “High Configuration” trolley, the cable is sectionable both from the unit side and the trolley side.

Handle the connectors with care.
Don't unplug by pulling the cable but grip the plug body.

FOR A CORRECT CONNECTOR INSERTION:

- HOLD THE SOCKET CONNECTOR IN ORDER TO MAKE LINED UP THE YELLOW ARROWS ON THE PARTS TO BE JOINED (END TO END)
- TAKE CARE OF INSERTING THE SOCKET CONNECTOR IN ORDER TO BE THE MOST POSSIBLE PARALLEL TO THE FIXED CONNECTOR. AVOID OBLIQUE INSERTIONS.
- TURN CLOCKWISE THE RUBBER RING NUT OF THE SOCKET CONNECTOR TILL HEARING THE CLICK THAT ENSURES THE SEAL

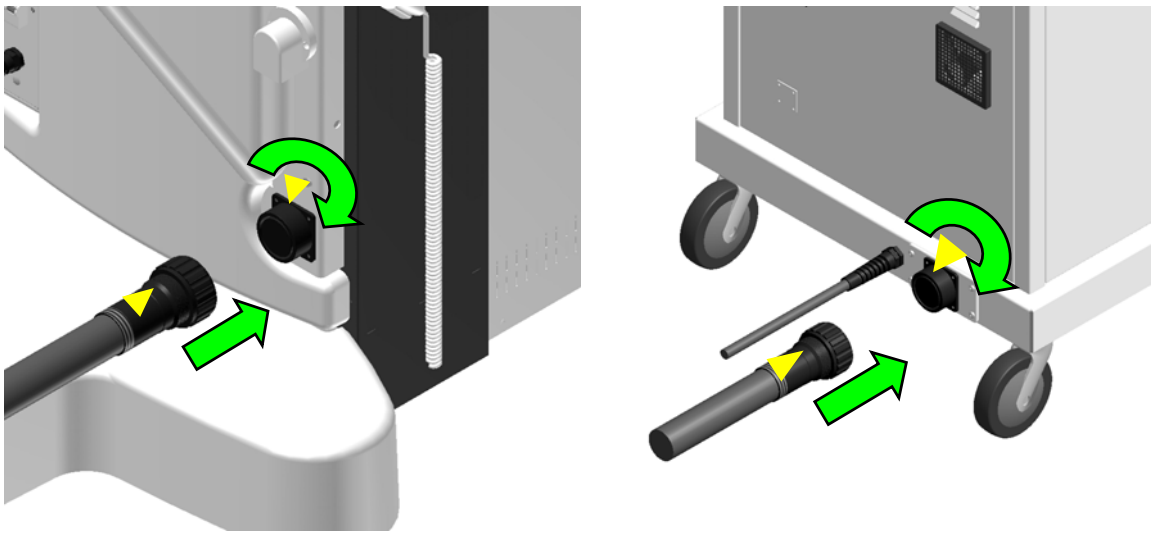
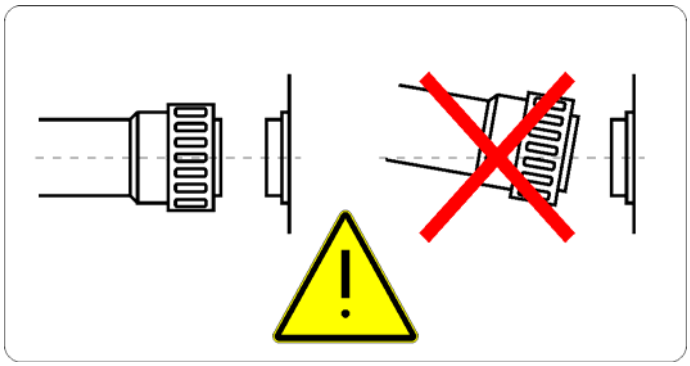


Fig. 17



3.3. Connection between Footswitch – Mobile Stand

The connection between these parts of ARCOVIS 3000 S/R is performed through a connector with press connection.

Handle the connectors with care.
Don't unplug by pulling the cable but grip the plug body.

- insert the connector of the footswitch in the appropriate outlet present on the mobile image intensifier (Fig. 18 pos. A);

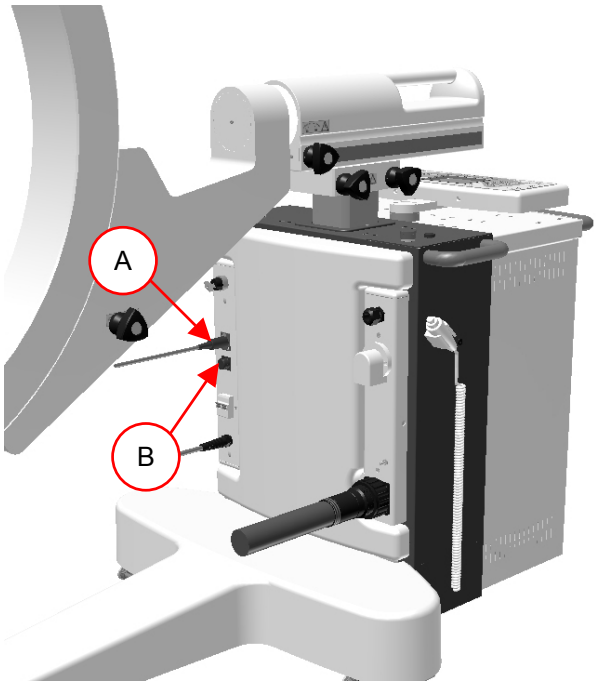


Fig. 18

3.3.1. Connection for External Interlocks (optional)

It is possible to use the unit as fixed position so that some warning signals are repeated outside the operative room.
In detail the repeated warning signals are for:

- a lamp that indicates the unit ON
- a lamp that indicates the x-ray emission
- a door opening contact that stops the x-ray emission.

The connection is performed through a multipolar connector with locking on ring nut (Fig. 18 pos. B). The prearrangement of the external signals wiring ***must*** be performed by the technical personnel.
For a correct connection it is necessary to:

- ensure that the unit is OFF;
- remove the terminal board closing cap;
- insert the connector of “external interlocks” in the proper socket present on the mobile image intensifier;
- ensure that the connector is screwed tight.

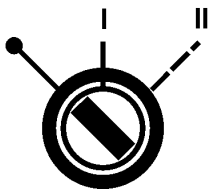
In order to remove the connection it is necessary:

- unscrew and remove the cable connector
- apply again the closing cap in the terminal board.

3.4. Unit ON / OFF

Unit with monitor aboard or with "BASE monitor TROLLEY"

The unit ARCOVIS 3000 S/R has got a switching-ON key with three car-type positions.

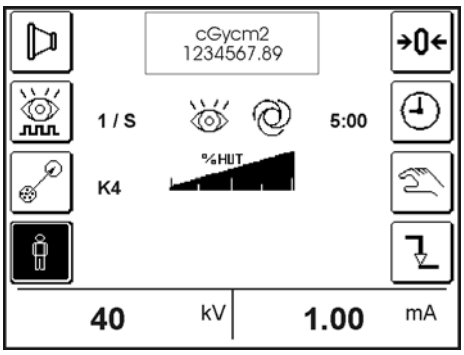


0 position	OFF	Key extraction position. Unit OFF
I position	WAIT	Stable position. Unit supplied by the mains
II position	START	Instable position. Unit ON

Connect the mobile image intensifier to the monitor trolley
(only for the version with monitor trolley) .
Connect the unit to the mains and put the magneto-thermic switch in "I" position.
Insert the ON key and rotate it clockwise in "WAIT" position
Rotate clockwise the ON key in "START" position and release it (push-button led for the mobile image intensifier console switching-ON lit).

Press the unit ON key.

After the test phase of the internal circuits and the software, the display shows the initial screen:

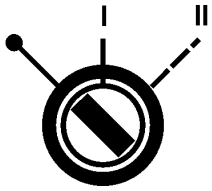


Activate the intended exposure mode according to what described in §3.6 "Use mode".

In order to turn the unit OFF, press OFF key, rotate the key in "OFF" position, put the magneto-thermic switch in "0" position.

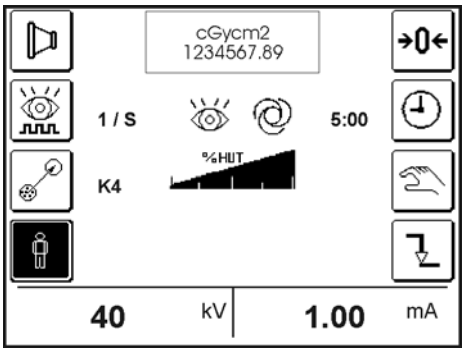
Unit with "HIGH CONFIGURATION monitor TROLLEY"

The unit ARCOVIS 3000 S/R has got a switching-ON key with three car-type positions mounted on the monitor trolley.



Position 0	OFF	Key extraction position. Unit OFF
Position I	WAIT	Stable position. Unit supplied by the mains
Position II	START	Instable position. Unit ON

Connect the trolley to the mains and put the magneto-thermic switch in "I" position.
Insert the switching-ON key and turn it clockwise in "WAIT" position.
Turn the switching-ON key clockwise in "START" position and release it (the switching-ON led will light up on the trolley control panel). The trolley is powered and it can work even without the unit connected.
Connect the mobile image intensifier to the monitor trolley. The connecting cable can be connected/disconnected even with the powered trolley.
Press the unit switching-ON push-button.
After the test phase of the internal circuits and the software, the display shows the initial screen:



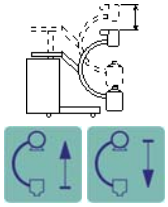
Activate the intended exposure mode according to what described in §3.6 "Use mode".
In order to turn the unit OFF, press OFF key, rotate the key in "OFF" position (on the trolley), put the magneto-thermic switch in "0" position (on the trolley).

3.5. Positioning

Don't move the mobile image intensifier or the C-arm with brakes ON.

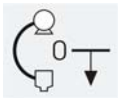
For movements use the proper handles (see §2.2.1).

Turn the unit ON (ref. §3.4)



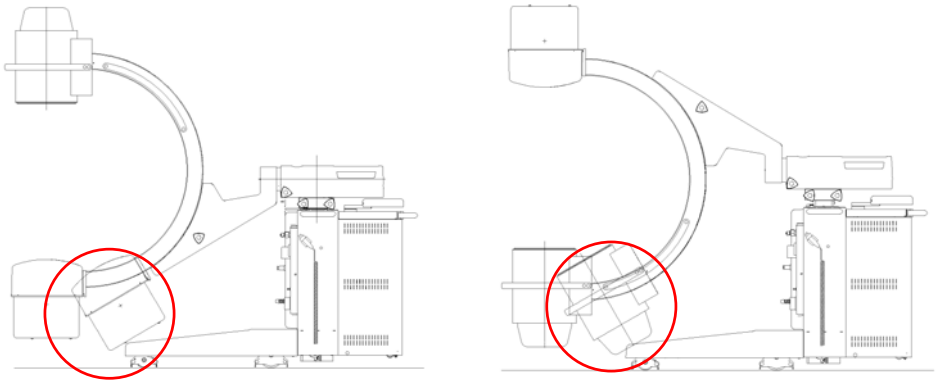
Adjust the arm height (motorized movement).

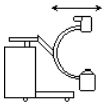
Use the control keys to change the position inside the travel.



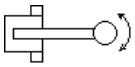
Use the Down key with the “Down Enable” key to perform the extra-travel downwards.

In order to avoid collisions between the monobloc (0,5K x 0,5K version) or I.I. tube (1K x 1K version) with the front unit leg, the vertical travel is limited downwards. It is possible to exceed this limit by pressing at the same time the down key placed on the control panel and the “Enable Down” push-button placed near the red emergency key. During this operation be careful to the monobloc or I.I. position in order to avoid collisions and damages to the unit.

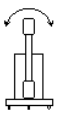




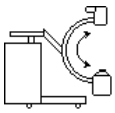
Adjust the horizontal position (manual movement).



Control the possible overview rotation of the C-arm (manual movement).



Adjust the C-arm rotation around the horizontal axis, the goniometric scale will indicate the rotation angle (manual movement).



Adjust the orbital position of the C-arm (manual movement).

When the positioning has been completed, check that all the braking systems are activated (see Fig. 8, Fig. 9).

Before performing an exposure, ensure that all the necessary precautions against radiation have been activated.
Before performing an examination, ensure that the residual exposure time indication is enough to the complete realization of diagnostic investigation.

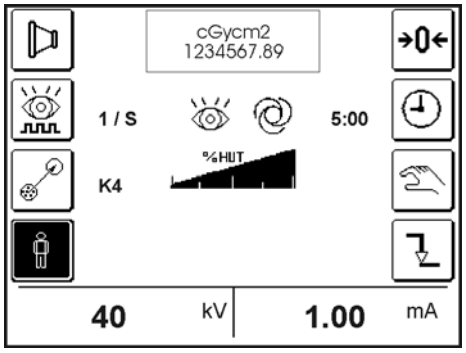
3.6. Use mode

The foreseen use modes are:

- **Continuous fluoroscopy (automatic and manual)**
- **Pulsed fluoroscopy (automatic and manual)**
- **Snap Shot**
- **Radiography**
- **Utility Mode**

3.6.1. AUTOMATIC CONTINUOUS FLUOROSCOPY

Turn the unit ON according to what described in §3.4 “Unit ON / OFF”. After the test phase of the internal circuits and the software, the unit is prearranged for the working in automatic fluoroscopy. The display appears as showed below:



Selection of the RADIOGRAPHY mode (§3.6.5)

Selection of the PULSED FLUOROSCOPY frequency. By pressing the key, the selection and the indication aside change (according to the installed memory).

FILTER selection. By pressing the key, the selection and the the indication aside change (according to the installed memory).

STANDARD ANATOMICS curve selection. When the function is selected, aside the key, the keys concerning the anatomic curves that can be selected appear.

ANATOMY curve for Fine Anatomic Parts or paediatrics.

ANATOMY curve for lungs.

ANATOMY curve for head, column, pelvis for sturdy patient.

When the key is selected, it appears in “negative”. By selecting one of these curves, the unit proposes proper kV-mA couples. It is not possible to modify the parameters.

(1/2) mA curve selection. When the key is selected, the STANDARD curve with the halved mA values is used.

Selection of the MANUAL mode (§3.6.2).

5:00

Indication of the residual Fluoroscopy time and the relative resetting key.
The time indicates the effective x-ray passage and it is updated every second.
When 5 minutes are expired, the key is crossed and the audible indicator intervenes.

0:00

At any minute, it is possible to press the reset key by taking the time back to the initial 5 minutes and by stopping the audible signal, if it is in working condition.
After 10 minutes of continuous fluoroscopy, the x-ray emission is interrupted. This supplementary time is resetting automatically at every release of the fluoroscopy footswitch.

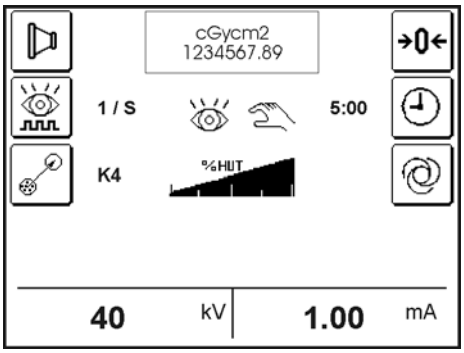
Key for the resetting of the dose value indicated in the central box. The key is active only if the dosimeter is installed and in working condition.
Hold down for at least two seconds to reset the displayed value.

Press the left pedal of the x-ray control footswitch.
After activating the x-ray control, the kV/mA values can be adapted automatically to the patient under examination in order to get the best possible image.
By pressing completely the pedal (second step), the image is stored.

X-ray emission LEDs on the keyboard and on the monitor trolley lit.

3.6.2. MANUAL CONTINUOUS FLUOROSCOPY

By entering MANUAL FLUOROSCOPY mode, the display appears in the following way:



Selection of the RADIOGRAPHY mode (§3.6.5)

Selection of the PULSED FLUOROSCOPY frequency. By pressing the key, the selection and the indication aside change (according to the installed memory).

FILTER selection. By pressing the key, the selection and the indication aside change (according to the installed memory).

Selection of the AUTOMATIC mode (§3.6.1).

5:00

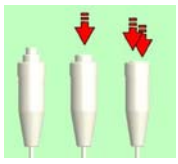
Indication of the residual Fluoroscopy time and the relative resetting key.
The time indicates the effective x-ray passage and it is updated every second.
When 5 minutes are expired, the key is crossed and the audible indicator intervenes.

0:00

At any minute, it is possible to press the reset key by taking the time back to the initial 5 minutes and by stopping the audible signal, if it is in working condition.
After 10 minutes of continuous fluoroscopy, the x-ray emission is interrupted. This supplementary time is resetting automatically at every release of the fluoroscopy footswitch.

Key for the resetting of the dose value indicated in the central box. The key is active only if the dosimeter is installed and in working condition.
Hold down for at least two seconds to reset the displayed value.

Press the left pedal to control the exposure.
After activating the x-ray control, the kV/mA values can be set by the operator. The exposure parameters variation allows to modify the image quality at the discretion of the operator. The automatic image control system is disabled.
By pressing completely the pedal (second step), the image is stored.
X-ray emission LEDs on the keyboard and on the monitor trolley lit.



The same functions of Fluoroscopy, both Automatic and Manual, and Storage can be performed also with the x-ray handswitch (if it is prearranged):

1° step: **fluoroscopy control**.
2° step: **image storage**.

3.6.3. AUTOMATIC AND MANUAL PULSED FLUOROSCOPY

Selection of the PULSED FLUOROSCOPY frequency. By pressing the key, the selection and the indication aside change (according to the installed memory).

Press the right pedal to control the exposure.
After the kV balance time, the exposure with the frequency set on the display is performed (the frequency changes according to the features of the installed memory).

In MANUAL mode, the kV and mAs value must be set by the operator. The exposure parameters variation allows to modify the image quality at the discretion of the operator.

X-ray emission LEDs on the keyboard and on the monitor trolley lit.

3.6.4. "SNAP SHOT"

No selection from the keyboard must be performed.

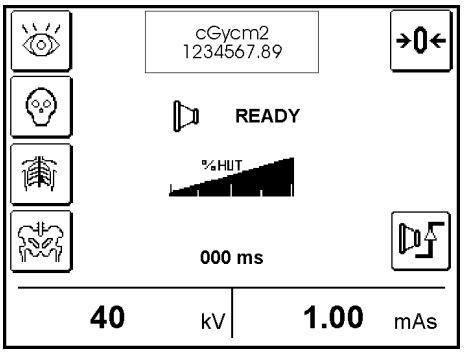
The "Snapshot" can be performed in Automatic and Manual Fluoroscopy mode without performing any additional choice on the keyboard.

Press the pedal of the X-ray control footswitch.
After the kV balance time, an exposure of about 1 sec controlled directly from the unit is performed. This exposure allows to get an image that is at high contrast and without background noise.

X-ray emission LEDs on the keyboard and on the monitor trolley lit.

3.6.5. RADIOGRAPHY

Select **Radiography**. The display appears as in the figure below:



Key for the FLUOROSCOPY mode selection (§3.6.1)

Key for the APR 1 mode selection. (Head)

Key for the APR 2 mode selection. (Spinal column)

Key for the APR 3 mode selection. (Pelvis)

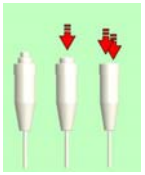
The chosen APR program proposes the default exposure parameters (kV, mAs, focus). The proposed data can be modified according to the requirements.

HiPower Radiography selection key

It appears only if the set mAs are lower than 2,2mAs.

Put the cassette holder at the input of the I.I. tube by coupling the two fixed locks and by locking the knob, insert the loaded x-ray cassette.

Set the kV and mAs parameters by operating on the relative increase and decrease keys placed under the indication of the value selected on the display.



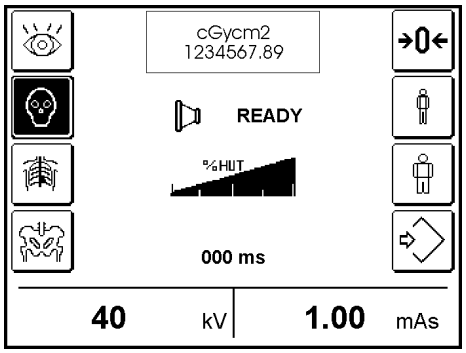
Use the whole length of the extensible cable to move away as much as possible from the irradiated area.
Press the x-ray handswitch and hold it down till the end of the exposure.

X-ray emission LED on the keyboard lit.

At the end of the exposure the performed exposure time is displayed.

APR radiography

By selecting the wished APR program, the relative key appears in negative and, on the right side of the screen, the keys concerning the selection of “slim patient” and “sturdy patient” appear.



Indication of the selected APR program.

Key to select the APR values for slim patient (visible only if an APR program is selected).

Key to select the APR values for sturdy patient (visible only if an APR program is selected).

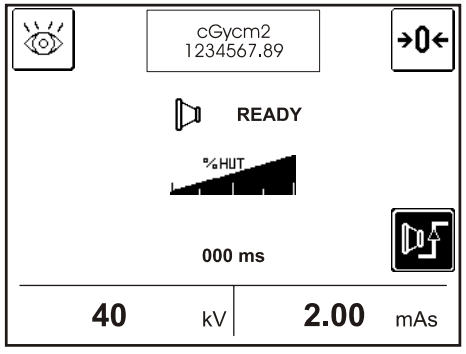
When the prearrangement for slim or sturdy patient is selected, the icon of the key in “negative” appears.

Data storage key

The proposed data can be modified at pleasure by the user. If the storage function is enabled in the USER SETUP menu (§3.6.10), the modified values can be saved in memory through the relative key. In case the modified data are not stored, at next return in Radiography mode, the default data will be re-proposed.

HiPower radiography

By selecting HiPower radiography, the relative key appears in negative, the keys concerning the APR programs disappear and the mAs are limited to a value lower than 2,2mAs. The kV can be set without limitations.



In this mode it is possible to perform a radiography at 5kW with rotating anode and at 3,5kW with fixed anode.

3.6.6. DURING THE EXAM

During every fluoroscopy exam, it is possible:

Select a different image enlargement.

Rotate the image position.

Overturn horizontally the image.

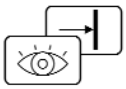
Enlarge or reduce in size the irradiated area through the iris diaphragm or the parallel shutters diaphragm.

Open completely the iris diaphragm automatically.

Open completely the shutter diaphragm automatically.

Rotate the position of the parallel shutters diaphragm

Alternate the various fluoroscopy modes simply by passing from a pedal to the other one of the fluoroscopy footswitch.



Store the current image in continuous fluoroscopy, by pressing the second pedal of the fluoroscopy footswitch.

Store the current image in pulsed fluoroscopy, by pressing the storage key.

3.6.7. AFTER THE EXAM

After every exam of fluoroscopy it is possible:

Review the stored images.

Rotate the image position.

Overturn horizontally the image.

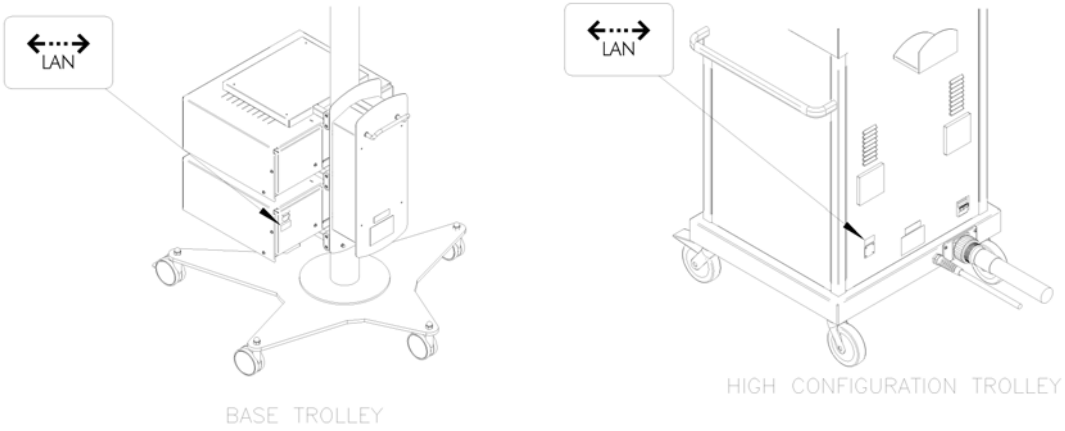
For additional images processing, refer to the user's manual of the memory installed on the unit.

3.6.8. IMAGES TRANSFER TO EXTERNAL NETWORK

In case of unit provided with DTU (Dicom Transmission Unit), it is possible to transfer the images to a network printer or to a central file for the possible filing or processing.

Transmission via cable (LAN)

In this case it is necessary to connect the unit to the network through a connecting cable (it is not supplied with the unit). The DTU, RJ-45 plug for connector, is present only on the trolleys showed in the following figure.
For the operation of transfer or printing, refer to the DTU User's Manual.

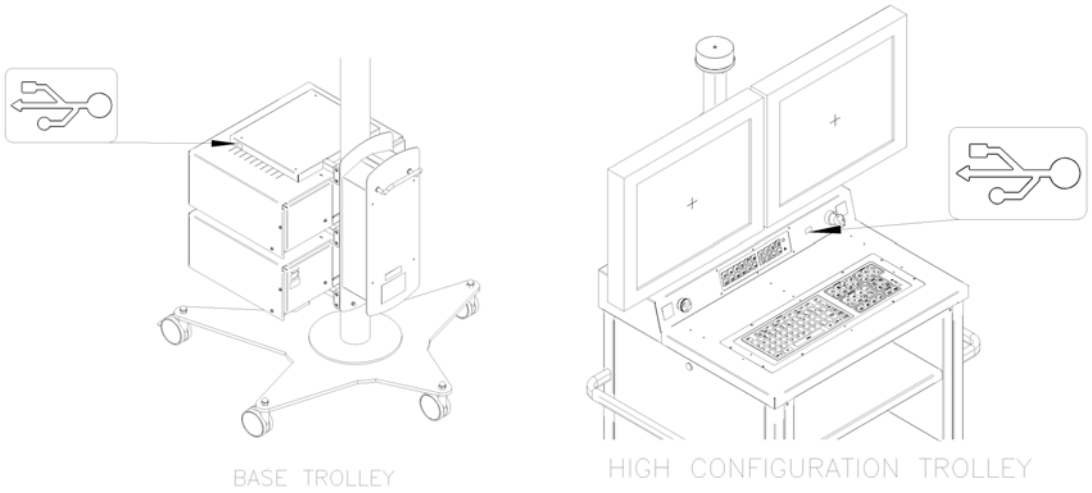


Wi-Fi Transmission (Optional only for HRP2000)

If the network adapter is installed on the unit and the Wi-Fi network is available, it is possible to transfer the images without cable in Wireless mode.
For the operation of transfer or printing, refer to the DTU User's Manual.

3.6.9. IMAGES TRANSFER ON USB SUPPORT

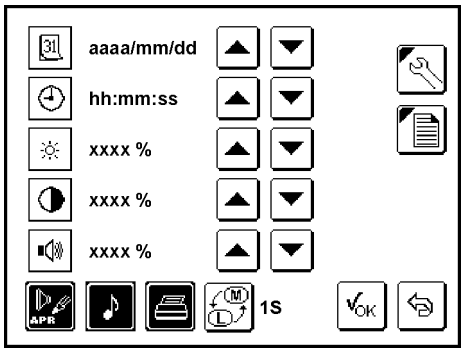
Series HRC and HRP memories allow images transfer on external USB support.



For transfer operations please make reference to the DTU user manual.

3.6.10. Utility Mode

Utility Mode is a particular use mode to set some unit parameters. It is accessible to the final user at any minute from the Automatic Continuous Fluoroscopy mode (§3.6.1). You enter Utility Mode by pressing on the keyboard the F1 key and, by holding it down, press the ENTER key.
The display appears as below:

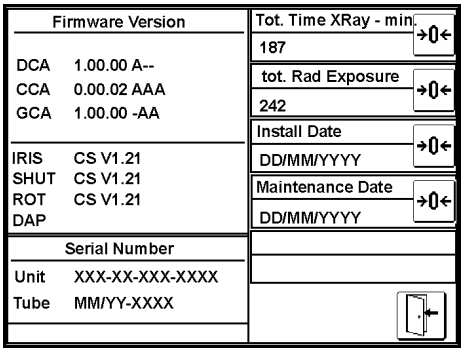


In this mode it is possible to set the following parameters:

	DATE	System date (yyyy/mm/dd format). It can be modified with the keys INC-DEC aside the icon.
	TIME	System time (hh:mm:ss format). It can be modified with the keys INC-DEC aside the icon.
	BRIGHTNESS	Display brightness adjustment (from 0 to 100%). It's modifiable by the INC-DEC keys, beside the icon.
	CONTRAST	Display contrast adjustment (from 0 to 100%). It's modifiable by the INC-DEC keys, beside the icon.
	VOLUME	Intensity of the buzzer volume (from 0 to 100%). It can be modified with the keys INC-DEC aside the icon. *It is not possible to modify the volume of the x-ray passage signals.*
	APR	Storage of the values associated to the APR exams. The activated function is indicated by the key in negative.
	CLICK	Enabling of the sound matched to the press of every key. The activated function is indicated by the key in negative.
	PRINT	Enabling of the dose printing. The activated function is indicated by the key in negative.
	FLIP	Selection of the commutating time between LIVE image and MEM image on single monitor (only for SBFM). It's modifiable from 1s to 5s, beyond infinite time ("…s") for applications with DVD recorder.
	SERVICE	Area reserved to service personnel.
	REPORT	Page with the firmware parameters display, serial number and data for service (see next page).
	OK	Key of modifications confirmation and exit from USER SETUP.
	ANNULLA	Key to exit from UTILITY MODE without saving the modifications.
	INC-DEC	Keys to increase and decrease the value displayed on their left.

Utility Mode - Report

The report screen is a particular screen accessible to the user in only reading. It does not include the data necessary to the normal unit use.



Firmware Version	Indication of the firmware versions loaded on the unit.
Serial Number	Indication of the monobloc and x-ray tube serial number.
Tot. Time Xray – min.	Counter of the total time (expressed in minutes) of the exposures in fluoroscopy mode with relative resetting key.
Tot. Rad Esposure	Counter of the total exposures number in Radiography mode with relative resetting key.
Install date	Unit installation data with relative resetting key. Datum inserted at the moment of the unit installation.
Maintenance Date	Limit date foreseen for the unit maintenance with relative resetting key. Datum automatically calculated by the unit according to the installation date or the date of the last maintenance (foreseen yearly).
	Key of resetting/activation. The activation/resetting keys are not accessible to the final user. For the possible data resetting it is necessary the intervention of Service.
	Key to exit from the display.

3.7. Shutdown procedure

This section describes the system shutdown procedure in order to ensure operators and patients' safety and a long unit life.

Don't disconnect the cable between the mobile image intensifier and the monitor trolley if the mobile image intensifier is not off.
Don't remove the connector from the mains outlet if the unit is not off.

When finished the examination, do the following:

If the unit is provided with DTU (Dicom Transmission Unit), in order to avoid the malfunctions due to the sudden lack of mains supply, it is necessary to perform first the correct shutdown of the DTU system.
Only after the DTU shutdown, proceed with the unit switching-OFF.

1. Position the mobile image intensifier in parking position (down, with the mechanical brakes ON).
2. Turn the mobile image intensifier OFF by operating on the "unit off" key of the control panel. Rotate the key in OFF position, remove and store it in a safe place.
3. Coil the footswitch cable and put it in the proper place.
4. Disconnect the mains cable and coil it again on the proper supports of the unit.
5. Disconnect the cable of the mobile image intensifier/monitor trolley and coil it on the proper supports of the monitor trolley
   (only for version with monitor trolley)
6. Park the monitor trolley by engaging the wheels brakes
   (only for version with monitor trolley)

4. MAINTENANCE

4.1. General warnings

As with any technical device, this system requires:

- proper use;
- regular checks by the user;
- regular maintenance by the authorized personnel

By taking these precautions, the working and the operative reliability of the unit are ensured.
The user of a x-ray unit is obligated to adopt such precautions in compliance with the accident-prevention standards, the standards on the medical products and other regulations.

As users of x-ray units it is necessary to take these precautions in compliance with the prevention standards formulated by the laws concerning the medical equipment.

The unit needs regular checks and maintenances. The purpose of the following warnings is to keep a good operating and safety level.
The unit includes mechanical parts that are subjected to wear in function of the use. After a long period of use, it is possible that the safety of the system may decrease due to the parts wear.
Regular checks and maintenance are necessary to protect the patient and the operator from damage due to the mechanical parts breakage.
The correct adjustment of the electro-mechanical and electronic modules is essential, as this has a direct influence on the unit operation, the image quality, the electrical safety and the exposure level of radiation to which the medical - nursering personnel is subjected.
The maintenance plan includes checks and prevention measures to be done by expressly authorized personnel and at the unit owner's charge.

In the replacement of any parts that can affect the units safe operation, use only original spare parts.

4.2. Checks and inspection by the user

The user has to check the possible presence of defects on the x-ray unit (see the following table). In case some operative defects or other deviations from the standard working occur, the user has to switch the unit OFF and inform the Service. The working of the x-ray unit can restart only when it has been repaired. The use of defected components can cause a risks increase for the safety or a high exposure to radiations.

If a faulty or malfunctioning unit is used, risks to the operators and patients can increase.

Summary of the periodical checks

Frequency	Reference	Method
Daily	Stability tests	
Daily	Faulty leds, damaged components, plates and warning signals	Inspection
Weekly	All cables and terminals (damages/breakages). Oil drippings and unusual noises in high voltage generator.	Inspection
Half-yearly	Operation of the arm movement limit switch. Accessories for the centering of the x-ray group and the image acquisition unit (marks, lock devices, contacts).	Inspection
Yearly	Contact the technical after-sale service to perform the constancy and reproducibility tests, as indicated by IEC 61223-1 and IEC 61223-2-11 standards, as well as the other operating tests of the unit, as instructed in the planned maintenance plan.	Inspection

4.3. Cleaning

Please take the following information into consideration before choosing a detergent:

- To clean plastic surfaces, simply use water and soap. If other detergents are used (e.g. with a high alcoholic content), the material will tend to break or opacify.
- Never use corrosive substances, abrasive solvents or detergents.

For the cleaning, please take the following actions:

- **Unplug the unit from the mains before cleaning it.**
- **Ensure that no liquid seeps into the unit, so as to avoid short-circuiting or corroding the electrical and electromechanical parts**.

- To clean enameled and aluminium surfaces, simply rub them with a wet cloth and a delicate detergent, after that rub them with a dry wool cloth.
- To clean chromium-plated surfaces, only rub them using dry wool clothes.

Do not use direct water jets or detergent for cleaning. The unit protection level for liquids is IPXO.

4.4. Disinfection

The used disinfection method must be in compliance with the standards and the directives in force concerning the disinfection and protection against explosions.

Never use corrosive substances, abrasive solvents or detergents.

In cases where there is a danger that disinfection products may form inflammable or explosive gaseous mixtures, always ensure that such gases have dispersed before re-using the equipment.

Before disinfecting the unit, unplug it from the mains.
Disinfect the unit parts, including accessories and connecting cables, by using only a wet cloth with a disinfecting substance.
Do not use disinfectant spray; it might penetrate the system.
To disinfect with a disinfectant spray the room where the unit is installed, turn it OFF, let cool it and cover it carefully with plastic sheets. Once the disinfectant gases have dispersed, remove the sheets and proceed with the disinfection with a cloth.

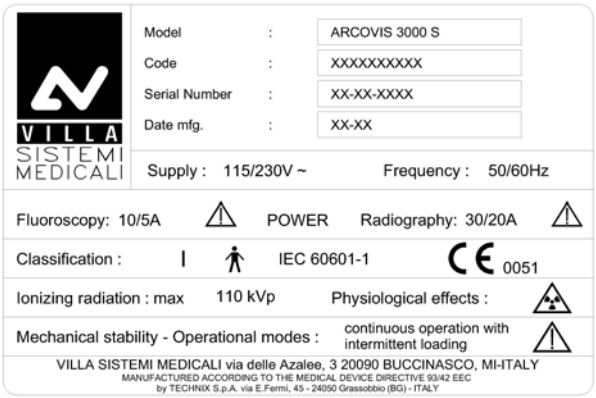
5. TECHNICAL DATA

5.1. Labels and symbols

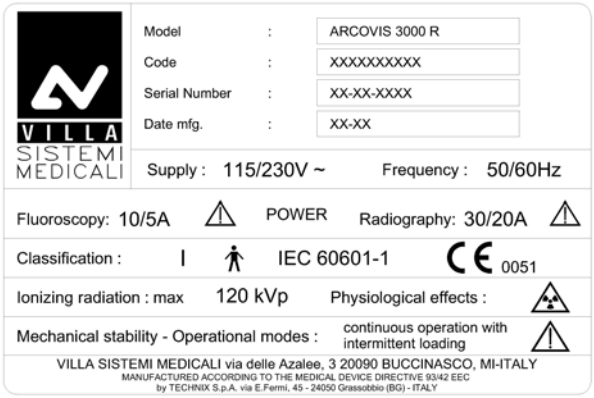
5.1.1. Unit labels

Pos. 1: S/N Label

Fixed Anode Version

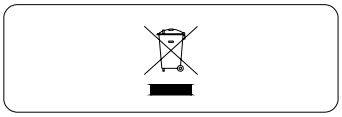


Rotating Anode Version



Pos. 2: WEEE Label

All versions



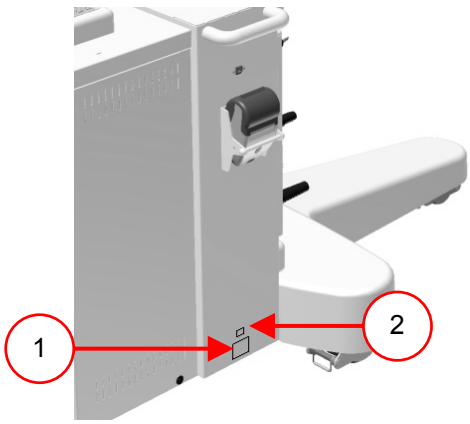


Fig. 19

5.1.2. Monitor trolley labels

Pos.1: S/N label (present only on versions with monitor trolley)

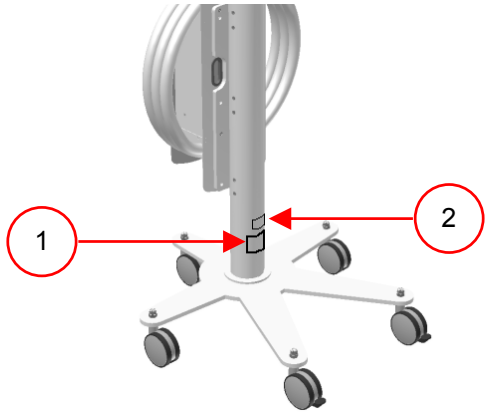


Fig. 20

Pos. 2: WEEE label

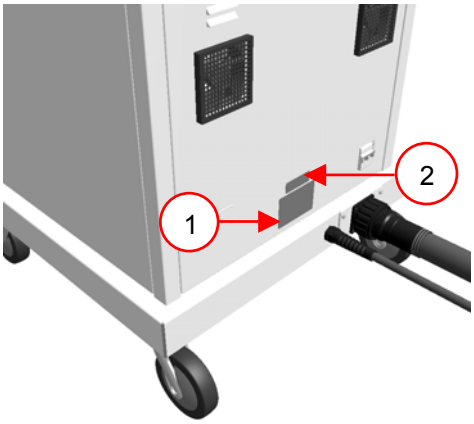


Fig. 21

5.1.3. Monobloc labels

Pos. 1: S/N label

Fixed Anode Version

Tank Unit	I-40S 3,5 RF	kVp max	110
Serial Number	XX/XX-XXXX	mA max	80
X-ray Tube	OX/110-5	Permanent filtration 1,4 Al/75 Total filtration >= 2,5 Al/75 incl. beam limiting device	
Serial Number	XXXXXX		
Focus (IEC60336)	0.5 1.5		

Rotating Anode Version

Tank Unit	I-40R 5 RF	kVp max	120
Serial Number	XX/XX-XXXX	mA max	110
X-ray Tube	X20P	Permanent filtration 1,4 Al/75 Total filtration >= 2,5 Al/75 incl. beam limiting device	
Serial Number	XXXXXX		
Focus (IEC60336)	0.3 0.6		

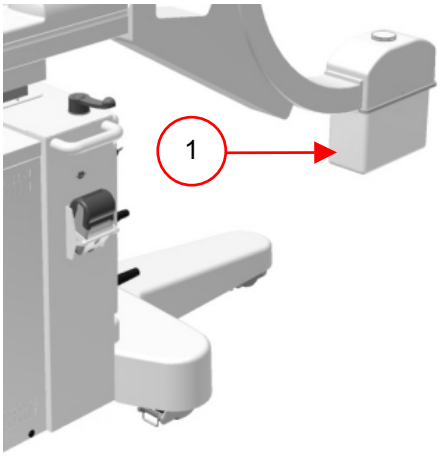


Fig. 22

5.1.4. IMAGE INTENSIFIER LABEL

Applied outside the image intensifier

I.I. Tube type A1234BCD * s/n 12345
Power supply type AB12345 ** s/n 123456

Codes present on the label in relation to the installed I.I. tube type:

Brand	***THALES***	***TOSHIBA***
* I.I. Tube type 9”/6”/4”	TH 9428 HP2 H542 VR13	E5764SDS-T1
** Power supply type	TH 7195	UP 33350

5.1.5. ANTISCATTERING GRID LABEL

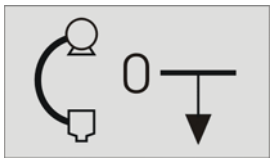
X-RAY GRID

Focus: 80 cm
Ratio 8:1 36 L/cm

5.1.6. UNIT SYMBOLS

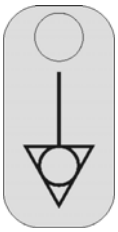
ON key label.

Emergency stop



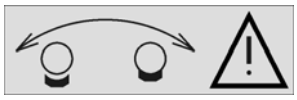
Label of “Enable Down” push-button, enabled arm extra-travel downwards

MAIN label

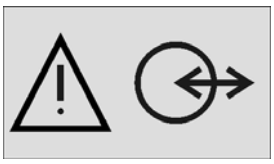


Equipotential node

WHEEE label



Brakes lock/release label.



External connections

Monitor connection
(only version with monitor aboard)

Footswitch

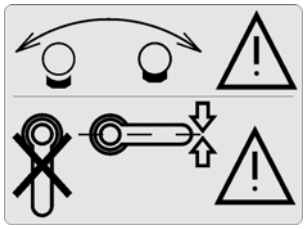
Hands squashing hazard

Fluoroscopy and radiography control

Clutch of the trolley - unit connection
(yellow inside)

Dose meter printer connection.

C-arm rotation degrees indication
(black inside)



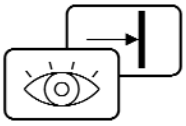
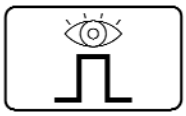
Label concerning the warning for the handle horizontal positioning.

	Additional DAP meter filtration label (only in case there is the dose meter accessory)
	Warning about laser radiation hazard (only in case there is the laser accessory).

5.1.7. MONITOR SYMBOLS

	Image contrast		
	Image brightness		
			on/off push

5.1.8. FLUOROSCOPY FOOTSWITCH SYMBOLS

	Fluoroscopy control + Image storage
	Pulsed fluoroscopy control
	Boost SNAPSHOT

5.2. Environmental conditions

Environmental Factor	In normal use	Warehouse and transport
Temperature	from 10°C to 40°C	from -25°C to 70°C
Relative Humidity	from 30% to 75% non-condensing	from 10% to 90% non-condensing
Pressure	from 700hPa to 1060hPa	from 500hPa to 1060hPa

5.3. Electrical data

Description	Fixed Anode Version	Rotating Anode Version
Voltage	230 Vac ±10% standard monophase 105 / 115 / 125 / 220 / 240 Vac ±10% monophase on request	
Frequency	50 Hz standard - 60 Hz on request	
Absorbed current in fluoroscopy	4,5A @ 230Vac 7,5A @ 115Vac	5A @ 230Vac 10A @ 115Vac
Absorbed current in radiography	20A @ 230Vac 28A @ 115Vac	20A @ 230Vac 30A @ 115Vac
Absorbed current in stand-by	1,0A @ 230Vac 1,7A @ 115Vac	1,0A @ 230Vac 2,0A @ 115Vac
Line compensation	Automatic	
Line resistance	<0,4Ω @230V <0,2Ω @115V	
Standard mains plug	16A @230Vac	
Classification EN60601-1 par.5: *Protection against electrical hazards* *Protection against direct and indirect contacts* *Protection against water seepage* *Use conditions*	 Class I equipment with applied part Type B common protection (IPXO) Continuous operating with intermittent load	
The unit is not suitable to be used where there exist mixtures inflammable with air or nitrous oxide		

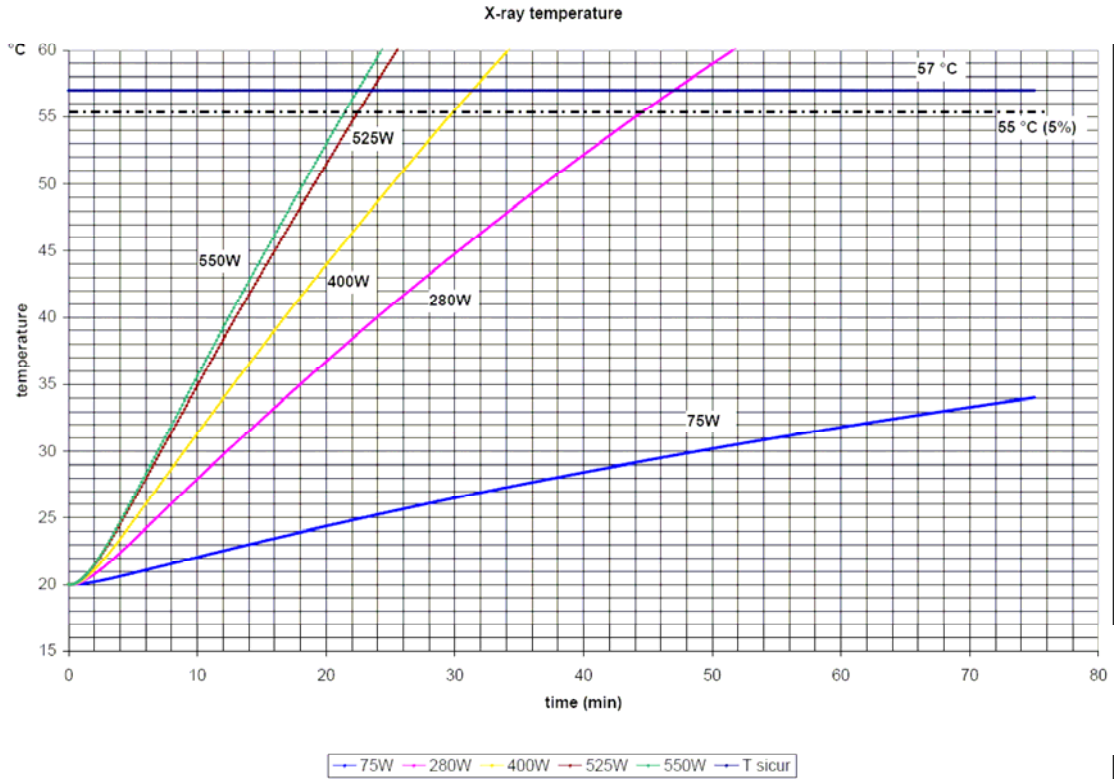
5.3.1. RADIOLOGICAL DATA

Description	Fixed Anode Version	Rotating Anode Version
Generator, power in DC current (IEC 60601-2-7)	2,5kW @100kV (100kV, 25mA, 100ms)	
Generator, max power in DC current	3,5kW (100kV, 35mA, 91ms) mAs < 2,2 @230Vac;	5kW (100kV, 50mA, 64ms) mAs < 2,2 @230Vac;
	2,5kW (100kV, 25mA, 128ms) mAs < 2,2 @115Vac)	3,5kW (100kV, 35mA, 91ms) mAs < 2,2 @115Vac
Max high voltage (fluoroscopy and radiography)	110kVp	120kVp
Frequenza Inverter	40 kHz	
Max. current in continuous fluoroscopy	8,0mA *(STANDARD curve)*	
Max. current in "SNAPSHOT" fluoroscopy	10mA	12mA (0,5K camera) 30mA (1K camera)
Max. current in radiography	25mA @230Vac 18mA @115Vac	
Max. mAs in radiography	125mAs @230Vac 90mAs @115Vac	

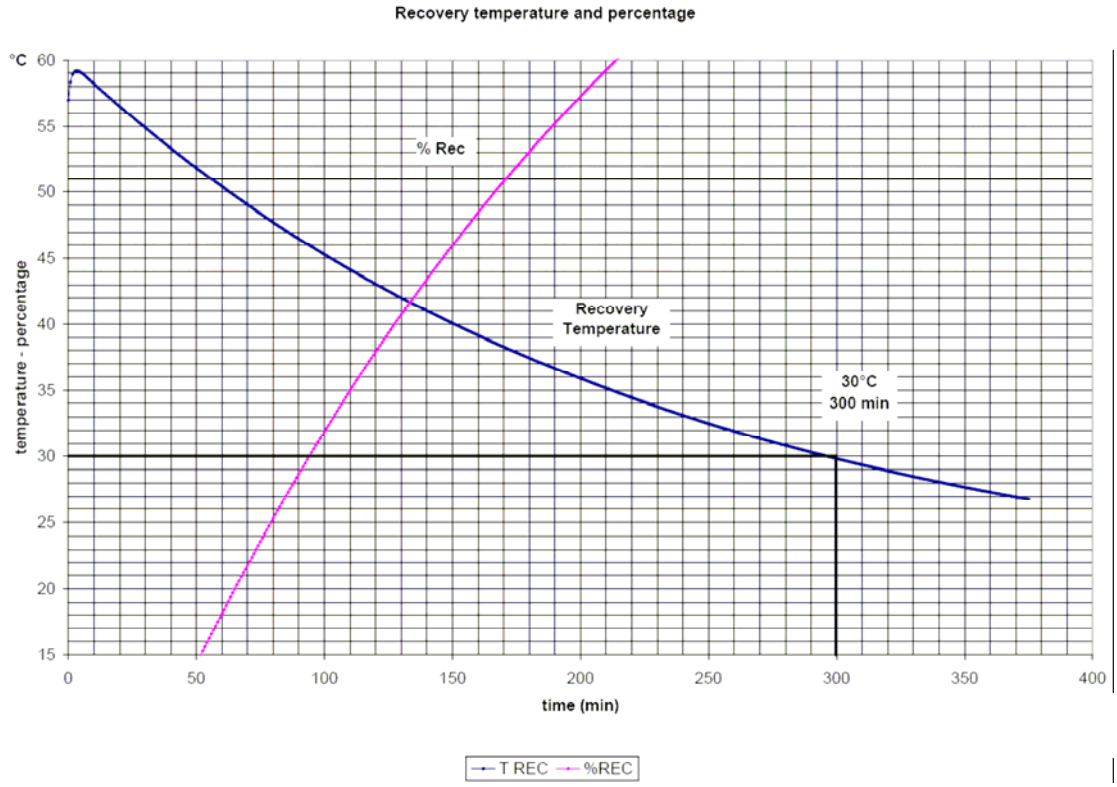
Description	Fixed anode version	Rotating anode version
Max. fluoroscopy time at 75W (75kV-1mA)	continuous	continuous
Max. fluoroscopy time at 280W (80kV-3,5A)	44 min	54 min
Max. fluoroscopy time at 400W (100kV-4mA)	29 min	38 min
Max. fluoroscopy time at 525W (70kV-7,5mA)	24 min	31 min
Max. fluoroscopy time at 550W (110kV-5mA)	21 min	---
Max. fluoroscopy time at 600W (120kV-5mA)	---	28 min
Max. fluoroscopy time	H.U Safety after 21 min of fluoroscopy @110kV, 5mA (550W).	H.U Safety after 28 min of fluoroscopy @120kV, 5mA (600W).
Cooling at 30°	300 min	420 min

Fluoroscopy time for fixed anode version

The values indicated in the graph refer to the trends calculated from the software safety procedures that are preventive concerning the bimetallic contact inside the monobloc that indicates the achievement of 57°C (134,60°F).

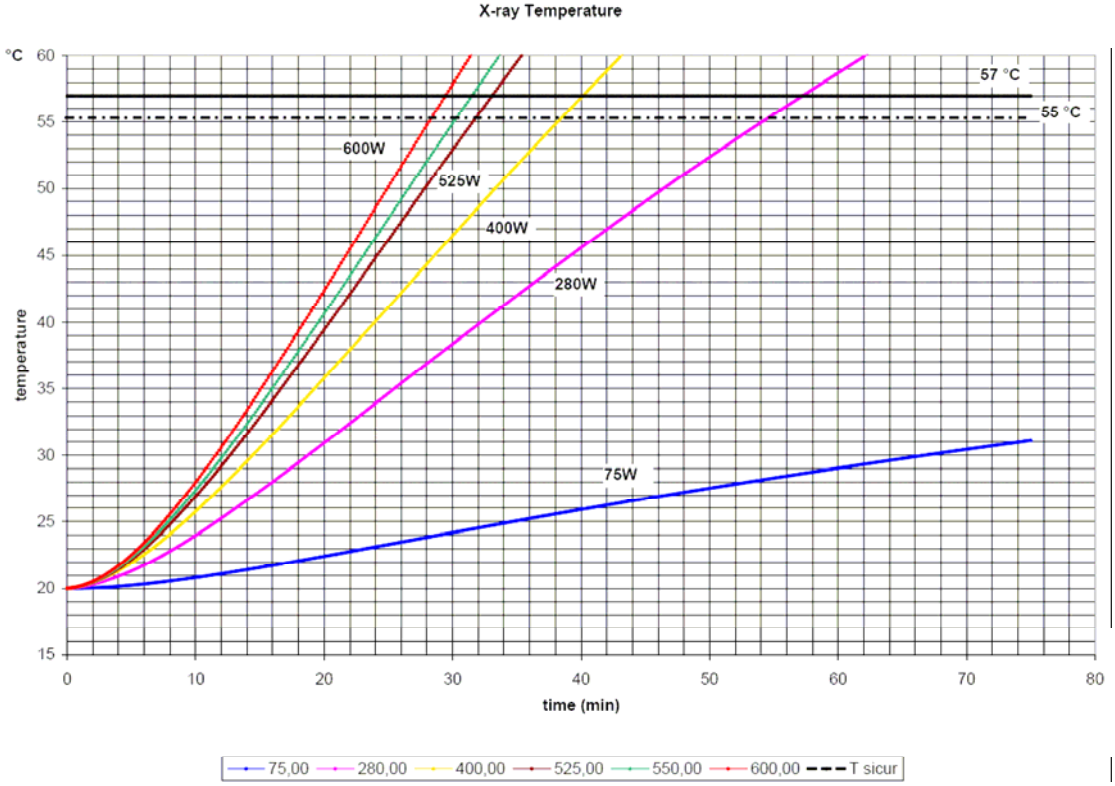


Recovery temperature and percentage

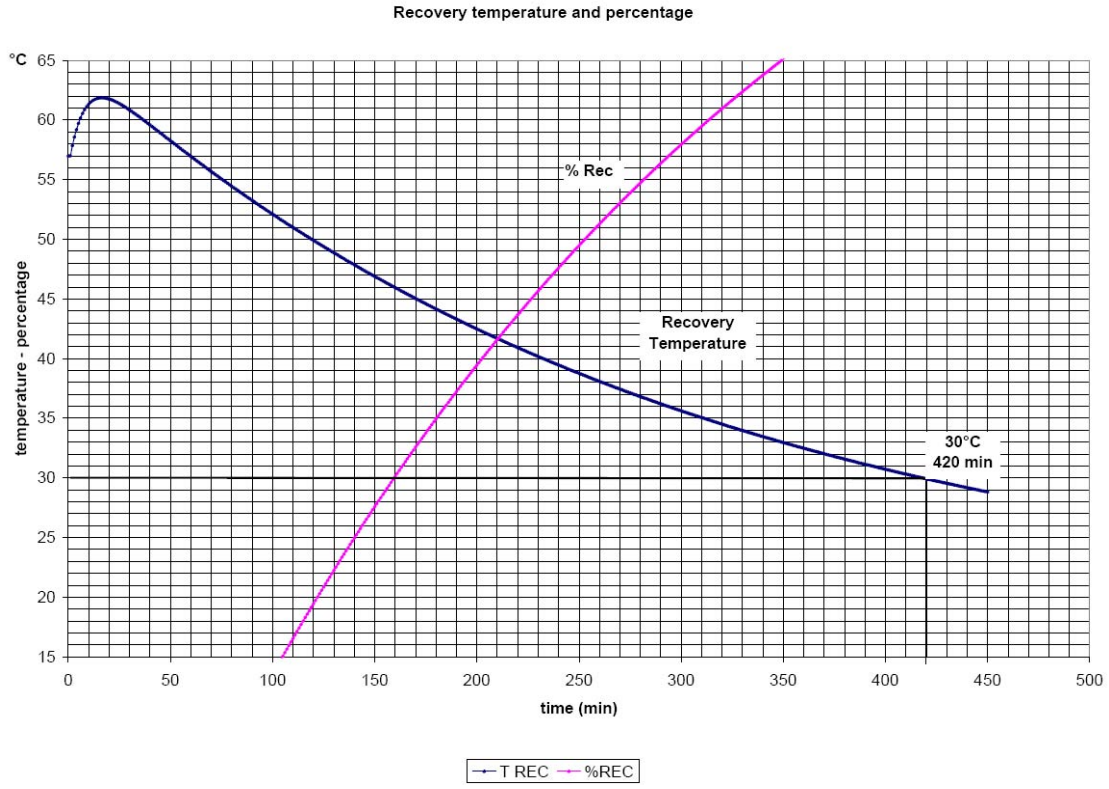


Fluoroscopy time for rotating anode version

The values indicated in the graph refer to the trends calculated from the software safety procedures that are preventive concerning the bimetallic contact inside the monobloc that indicates the achievement of 57°C (134,60°F).



Recovery temperature and percentage



5.3.2. COLLIMATOR

Description	Data
Model	With iris: mod.R605/027A/DASM With iris and parallel shutters: Mod.R605/027/DASM
Fields dimension (DF 100cm- 39"): *round field delimitation* *elliptical field delimitation*	 5±23cm 0±23cm
Leakage radiation *(EN60601.1.3 par.29.204.3)*	<40mR/h
Inherent filtration (EN60601.1.3)	0mm
Classification EN60601-1 par.5: *Protection against electrical hazards* *Protection against direct and indirect contacts* *Protection against water seepage*	 Class I equipment with applied part Type B common protection (IPXO)

5.3.3. X-RAY GROUP

X-ray housing data

Description	Fixed Anode Version	Rotating Anode Version
Monobloc model	**I-40S 3,5 RF**	**I-40R 5 RF**
Max. power (100kV – 35mA) (IEC 601-1)	3,5 kW	
Max. tube voltage	110KV	120kV
Ripple at the max. power	<2%	
kV Rise time at max. power	<1ms	
Mechanical housing features		
Half-value layer @75kV	2,0mmAl	
Min. inherent filtration @75kV	1,4mmAl	
Weight	15,0kg	19,0kg
Thermal housing features		
Thermal capacity	500kJ (670kHU)	600kJ (800 kHU)
Thermal safety	57°C ±3°C	
Compensation lung	410cm^3	
Continuous thermal dissipation	75W, 102 HU/sec, 6120 HU/min	
Max. housing temperature	60°C	
X-ray tube filament power supply		
Max. current (rms)	500mA	500mA
Leakage radiation (CEI EN 60601-1-3)		
	<100mR/h a 100cm	

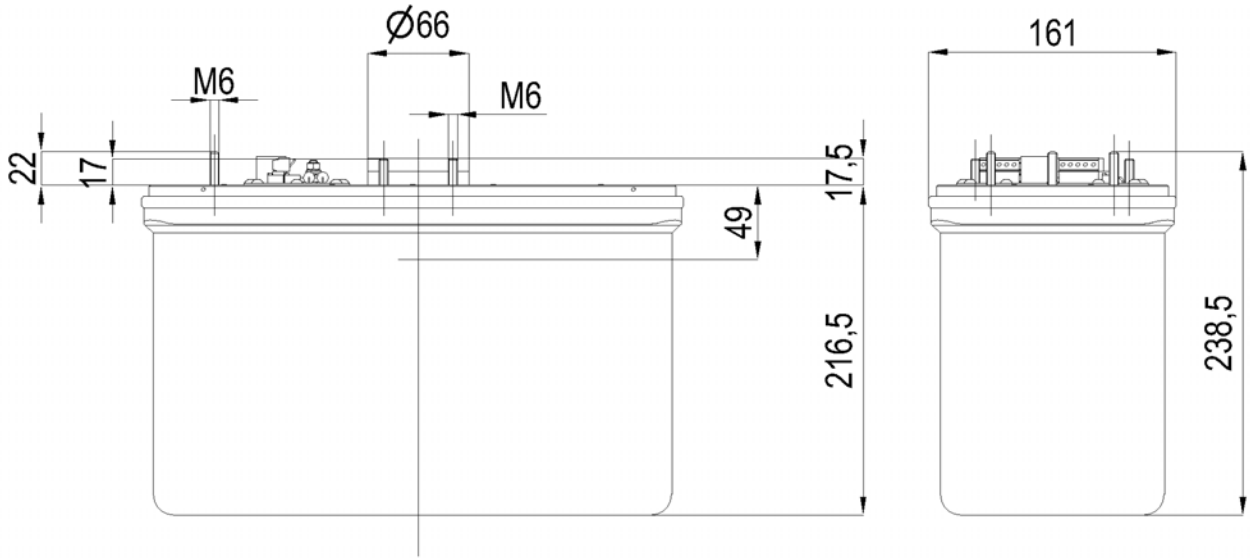
In case it is not used for more than three months, proceed to the tube reset in the following way:

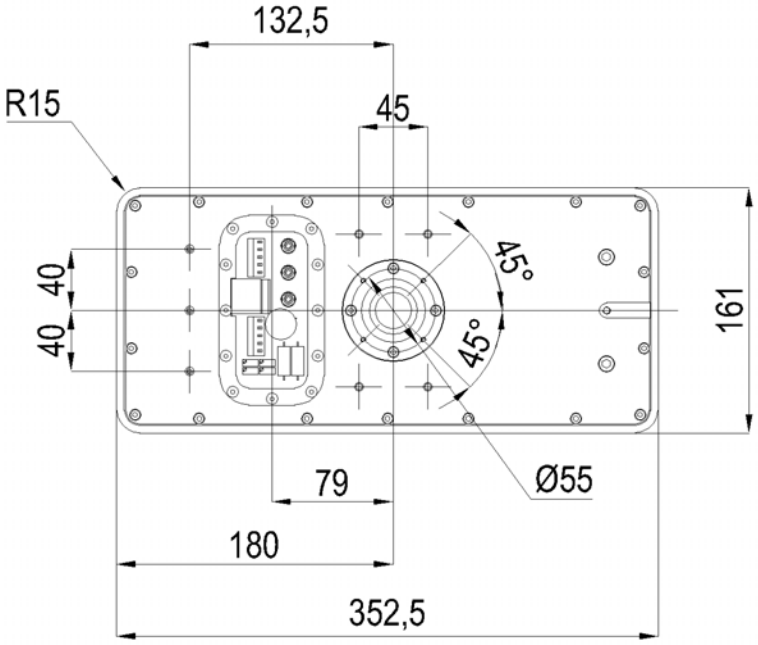
Working parameters			Exposure time		To be repeated
kV		mA/mAs	time ON	time OFF	
Fluoros	70	3	5'	5'	5 times
Radiog	70	12,5mAs	0,5 sec	30 sec	Increase of 5kV till kVmax.

If during the procedure some working irregularities or anomalies are found, it is necessary to stop it for at least half an hour and start it again from the beginning.

***Monobloc RX* I-40S 3,5 RF**

dimensions

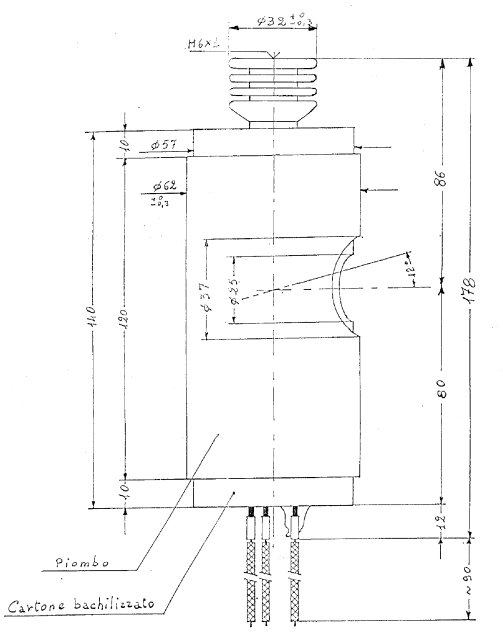




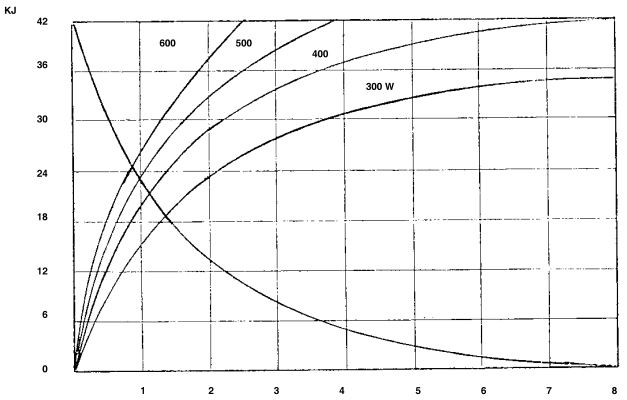
Data of x-ray fixed anode insert

X-RAY INSERT MODEL CEI OX/110-5 PHU 0,5/1,5	
Max. peak voltage	110kVP
Max. filament current	4,5A
Nominal foci dimension: *Small focus* *Large focus*	 0,5mm 1,5mm
Nominal anodic power: *Small focus* *Large focus*	 800W 4000W
Anode material	Tungsten
Anode inclination angle	12°
Thermal anode capacity	40kJ (54kHU)
Max. continuous thermal dissipation	400W (536 HU/sec)
Min. inherent filtration	0,5mm Al
Tube material	Glass

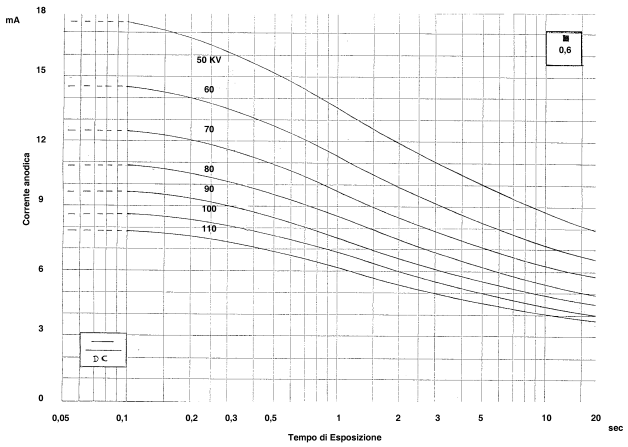
Mechanical dimensions



Thermal anode feature

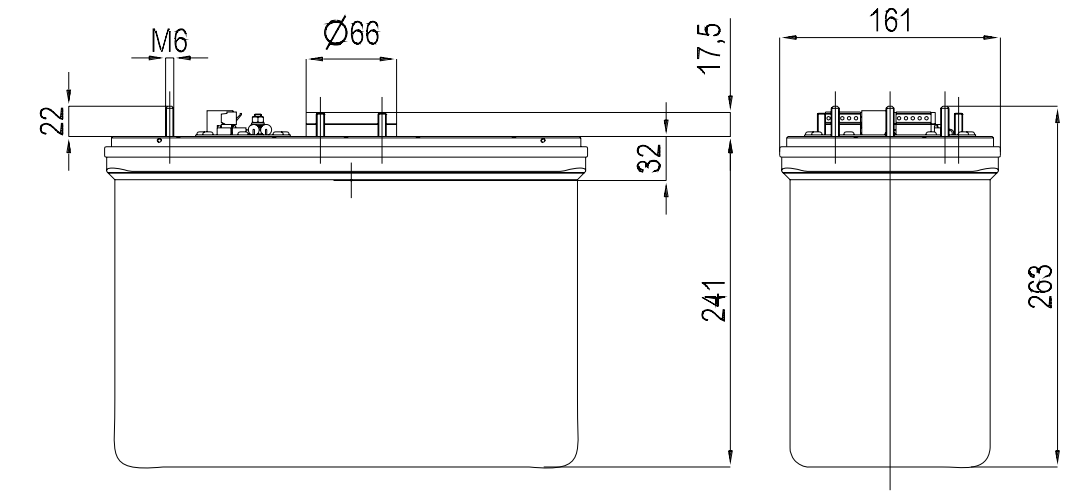


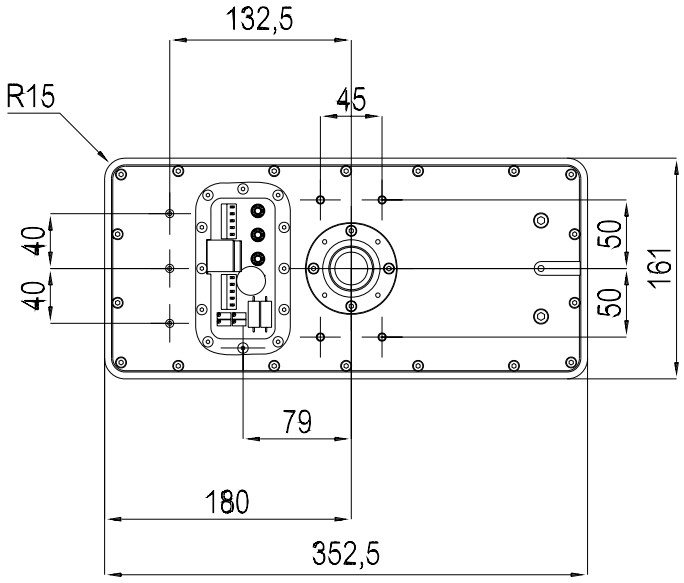
Load curves (■ - 3~)



Monobloc I-40R 5 RF

dimensions

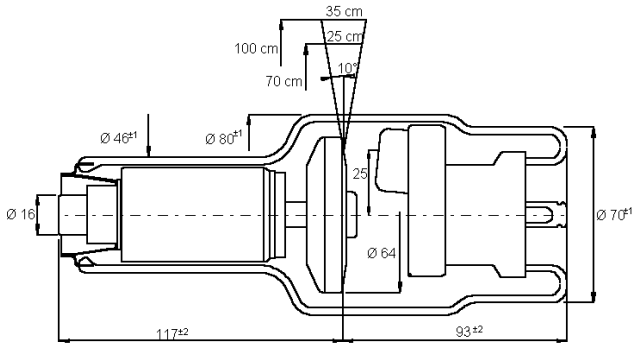




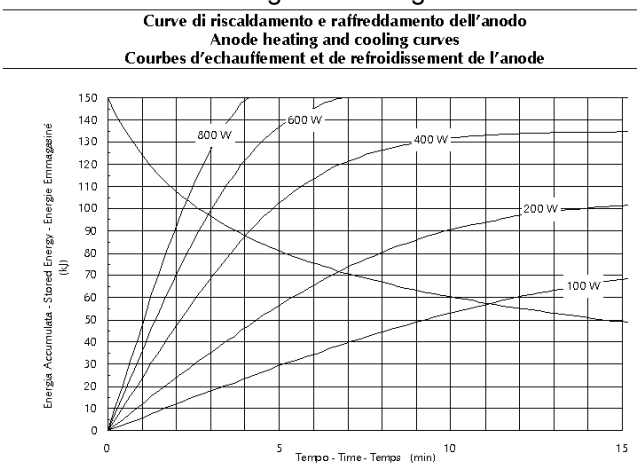
Data of the x-ray rotating anode insert

X-RAY INSERT MODEL IAE X20P 0,3-0,6	
Max. peak voltage	130kVP
Max. filament current	5,4A
Nominal foci dimension: *Small focus* *Large focus*	 0,3mm 0,6mm
Nominal anodic power: *Small focus* *Large focus*	 5kW 17kW
Anode material	*Rhenium / Tungsten / Molybdenum*
Anodic diameter	*64mm*
Anode inclination angle	*10°*
Thermal anode capacity	*150kJ (200kHU)*
Max. continuous thermal dissipation	*300W*
Min. inherent filtration	*0,7mm Al*
Tube material	*glass*

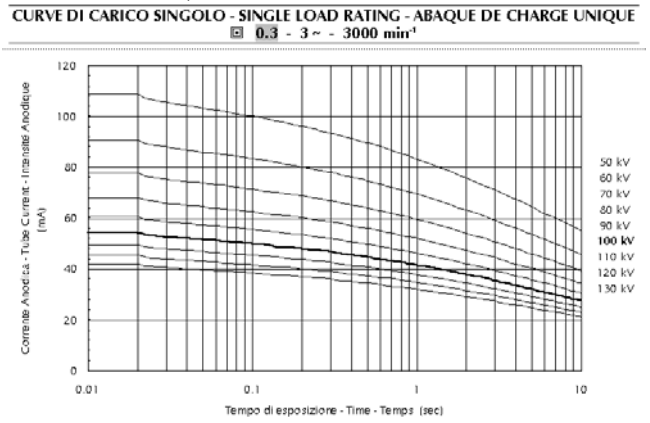
Mechanical dimensions



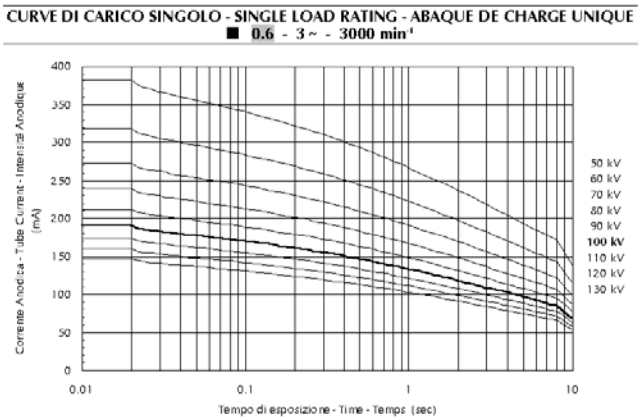
Anode heating and cooling curves



0,3mm focus load curves



0,6mm focus load curves



5.3.4. TOTAL UNIT HALF-VALUE LAYER

Description	Fixed Anode Version	Rotating Anode Version
Half-value layer @75kV	2,8mmAl	2,8 mmAl
Half-value layer @110kV	-	-
Half-value layer @120kV	-	-

5.3.5. TOTAL UNIT FILTRATION

Description	without DAPMeter	with DAPMeter
Monobloc	1,4 mmAl	1,4 mmAl
Collimator	0 mmAl	0 mmAl
Permanent additional filter	1 mmAl	1 mmAl
Monobloc cover	0,1 mmAl	0,1 mmAl
Permanent additional DAPMeter filtration	---	0,3 mmAl
Total unit filtration @75kV	**2,5 mmAl**	**2,8 mmAl**

Required min. filtration *According to the IEC 60601-1-3 par. 29.201.5*	≥ 2,5 mmAl eq.

5.4. Exposure mode: fluoroscopy

5.4.1. CONTINUOUS FLUOROSCOPY

Description	Fixed Anode Version	Rotating Anode Version
Small focus (IEC 336)	0,5mm	0,3mm
kV variation range	40÷110kV	40÷120kV
mA variation range	0,5÷8mA	0,5÷8mA
kV-mA relationship	Standard: 40kV / 0,5mA 80kV / 7,6mA 110kV / 8mA	Standard: 40kV / 0,5mA 80kV / 7,6mA 120kV / 8mA
	Last Image Hold	
Safety timer	Audible alarm after 5' X-ray stop after 10' of uninterrupted fluoroscopy (IEC 60601-2-7 §29.1.104).	

5.4.2. PULSED FLUOROSCOPY

Camera 0,5K²

Description	Fixed Anode Version	Rotating Anode Version
Small focus (IEC 336)	0,5mm	0,3mm
Exposure frequency (selectable from console)	2imm/sec, 1imm/sec, 1imm/2sec, 1imm/3sec, 1imm/5sec.	
Xr flash time	Min. time for the best image quality	
Other features as per Continuous Fluoroscopy		

Camera 1K²

Description	Fixed Anode Version	Rotating Anode Version
Small focus (IEC 336)	0,5mm	0,3mm
Exposure frequency (selectable from console)	2/sec, 1/sec, 1/2sec	
Xr flash time	Min. time for the best image quality	
Other features as per Continuous Fluoroscopy		

5.4.3. ONE-SHOT FLUOROSCOPY

0,5K² Camera

Description	Fixed Anode Version	Rotating Anode Version
mA variation range	1÷10mA	1÷12mA
Xr flash time	< 1sec	
Acquisition obtained from the integration of 16 continuative readings.		
Automatic storage in non-volatile RAM memory according to the memory.		
Other features as per Continuous Fluoroscopy		

1K² Camera

Description	Fixed Anode Version	Rotating Anode Version
mA variation range	1÷10mA	2,5÷30mA
Xr flash time	< 1sec	
Acquisition obtained from the integration of 16 continuative readings.		
Automatic storage in non-volatile RAM memory according to the memory.		
Other features as per Continuous Fluoroscopy		

5.4.4. (1/2) mA FLUOROSCOPY

Description	Fixed Anode Version	Rotating Anode Version
mA variation range	0,25÷4mA	0,25÷4mA
kV-mA relationship	40kV / 0,25mA 80kV / 3,8mA 110kV / 4mA	40kV / 0,25mA 80kV / 3,8mA 120kV / 4mA
Other features as per Continuous Fluoroscopy		

5.4.5. APR FLUOROSCOPY

Camera 0,5K²

Description	Fixed Anode Version	Rotating Anode Version
APR 1 (Fine anatomic parts or for paediatric use)	40kV / 0,7mA 80kV / 6,4mA 110kV / 6,6mA	40kV / 0,7mA 80kV / 6,4mA 120kV / 6,6mA
APR 2 (lungs)	40kV / 0,5mA 80kV / 7mA 110kV / 6mA	40kV / 0,5mA 80kV / 7mA 120kV / 5,5mA
The curves cannot be modified by the operator.		

Camera 1K²

Description	Fixed Anode Version	Rotating Anode Version
APR 1 (Fine anatomic parts or for paediatric use)	40kV / 0,7mA 80kV / 6,4mA 110kV / 6,6mA	40kV / 0,7mA 80kV / 6,4mA 120kV / 6,6mA
APR 2 (lungs)	40kV / 0,5mA 80kV / 7mA 110kV / 6mA	40kV / 0,5mA 80kV / 7mA 120kV / 5,5mA
APR 3 (Head, spinal column, pelvis)	---	40kV / 1mA 70kV / 15mA 120kV / 9mA
The curves cannot be modified by the operator.		

kV-mA relationship of camera 0,5K²

kV	mA (Fixed Anode Version)					
	Standard	mA(1/2)				Snapshot
40	0.50	0.25	0.70	0.50		1.00
50	2.50	1.25	2.40	1.00		4.00
60	5.00	2.50	4.20	3.00		7.00
70	7.50	3.75	5.60	5.00		10.0
80	7.60	3.80	6.40	7.00		10.0
90	7.70	3.85	6.40	6.50		9.00
100	7.80	3.90	6.40	6.25		8.00
110	8.00	4.00	6.60	6.00		8.00
kV	**mA (Rotating Anode Version)**					
	Standard	mA(1/2)				Snapshot
40	0.50	0.25	0.70	0.50		1.00
50	2.50	1.25	2.40	1.00		4.00
60	5.00	2.50	4.20	3.00		7.00
70	7.50	3.75	5.60	5.00		10.0
80	7.60	3.80	6.40	7.00		12.0
90	7.70	3.85	6.40	6.50		12.0
100	7.80	3.90	6.40	6.25		11.0
110	8.00	4.00	6.60	6.00		10.0
120	8.00	4.00	6.60	5.50		9.00

kV-mA relationship of camera 1K²

kV	mA (Fixed Anode Version)					
	Standard	mA(1/2)				Snapshot
40	0.50	0.25	0.70	0.50		1.00
50	2.50	1.25	2.40	1.00		4.00
60	5.00	2.50	4.20	3.00		7.00
70	7.50	3.75	5.60	5.00		10.0
80	7.60	3.80	6.40	7.00		10.0
90	7.70	3.85	6.40	6.50		9.00
100	7.80	3.90	6.40	6.25		8.00
110	8.00	4.00	6.60	6.00		8.00
kV	**mA (Rotating Anode Version)**					
	Standard	mA(1/2)				Snapshot
40	0.50	0.25	0.70	0.50	1.00	2.50
50	2.50	1.25	2.40	1.00	4.00	7.50
60	5.00	2.50	4.20	3.00	10.0	15.0
70	7.50	3.75	5.60	5.00	15.0	25.0
80	7.60	3.80	6.40	7.00	13.0	30.0
90	7.70	3.85	6.40	6.50	12.0	25.0
100	7.80	3.90	6.40	6.25	11.0	20.0
110	7.90	3.95	6.60	6.00	10.0	15.0
120	8.00	4.00	6.60	5.50	9.00	10.0

5.5. Exposure mode: radiography

Two points technique, kV and mAs selection

Description	Fixed Anode Version	Rotating Anode Version
Large Focus (IEC 336)	1,5mm	0,6mm
kVp range	40÷110kV	40÷120kV
mA range	@ 230Vac 25 mA fixed from 40kV to 100kV; 22 mA at 110kV @ 115Vac 18 mA fixed from 40kV to 100kV; 16 mA at 110kV	@ 230Vac 25 mA fixed from 40kV to 100kV; 20 mA at 120kV @ 115Vac 18 mA fixed from 40kV to 100kV; 15 mA at 120kV
mAs range	@ 230Vac 1 – 125 mAs from 40 to 100kV 1 – 100 mAS from 101 to 110kV in 42 steps, curve R'20	@ 230Vac 1 – 125 mAs from 40 to 100kV 1 – 100 mAS from 101 to 120kV in 42 steps, curve R'20
	@ 115Vac 1 – 90 mAs from 40 to 100kV 1 – 80 mAS from 101 to 110kV	@ 115Vac 1 – 90 mAs from 40 to 100kV 1 – 71 mAs from 101 to 120kV
HiRad mA range HiRad (mAs < 2,2)	@ 230Vac 35 mA fixed from 40kV to 100kV; 31 mA at 110kV	@ 230Vac 50 mA fixed from 40kV to 100kV; 30 mA at 120kV
	@ 115Vac 25 mA fixed from 40kV to 100kV; 22 mA at 110kV	@ 115Vac 35 mA fixed from 40kV to 100kV; 20 mA at 120kV
HiRad Exposure times range	@ 230Vac 28÷90 msec	@ 230Vac 20÷64 msec
	@ 115Vac 40÷128 msec	@ 115Vac 28÷90 msec
Exposure times range	0,04÷5 sec	
Duty cycle	Calculated according to the anode dissipation	

5.5.1. APR RADIOGRAPHY

Description		Norm		
	APR 1 (Head)	77kV 56mAs	74kV 45mAs	80kV 71mAs
	APR 2 (Lungs)	110kV 11mAs	107kV 9mAs	110kV14mAs
	APR 3 (Pelvis)	85kV 22mAs	82kV 28mAs	88kV 18mAs
The curves can be modified by the operator.				

5.6. Image system

5.6.1. IMAGE INTENSIFIER (1)

Description	Triple 9/6/4”

Brand	Thales
Model	TH 9428 HP2 H542 VR13
Fields Number	3
Nominal Input Diameter	230 mm
Output Image Diameter	20 mm
Output Window Thickness	3,6 mm
Useful Input Field Size	215/160/120 mm
Typical Resolution (Central)	48/56/64 lp/cm
Conversion Factor ($Cd/m^{-2}/mR/s^{-1}$)	240/120/60
Contrast Ratio	23:1/25:1/30:1
Integral Image Distortion	4% / 2% / 1%
Differential Distortion at 90% radius	15% / 6% / 3%
DQE at 59.5 kV	65%
"All metal" Technology	Yes
Input Screen "Hi-Res."	Yes
MTF at 10 Lp/cm	60/65/70%
MTF at 20 Lp/cm	25/30/40%
Low frequency drop LDF	7/6/5%
Fixed Antiscattering Grid	Ratio 8:1, 36 shutters/cm, focus 80 cm, material aluminum

(1) According to IEC standard IEC from 1262-1 to 1262-6

5.6.2. TV CHAIN AND MONITOR

TV chain with CCD 0,5K x 0,5K

Description	***Data***
Camera	
Camera technology	*CCD at low persistence of ½" (470.000pixels)*
Video standard	*CCIR 625/50Hz interlaced with matrix 752x 582 pixels*
Aspect ratio	*4:3* interlaced scanning
Band width	*20 MHz ± 3dB*
Signal-noise ratio	*65 dB*
Resolution	*20 lines-pairs (on 6" image intensifier)*
Gamma correction	*0,4 o 1*
Automatic video level compensation	*Yes*
Dynamic contrast Shading	*Yes*
Video output A/D converter	*10 bit*
Power supply	*24Vdc ±20% 20W*
Control Unit Dimensions	*226x120x46 mm, 0,550Kg*
Camera Head Dimensions	*Ø85x87mm, standard*
Camera Head Weight	*0.460Kg, standard*

TV chain with CCD 1K x 1K

Description	***Data***
Camera	
Camera technology	*CCD interlain progressive scanning*
Active pixels	*1024x1024*
Acquisition	*Matrix 1024x1024 pixel, 10bit, rate 25fps*
Resolution contrast	*1024 grey levels*
Sensitivity	*0,2 LUX (PB20 light)*
Noise signal ratio	*60db*
Weight (board + optics)	*1400gr*
Camera head power supply	*24Vdc 200mA*
Receiver power supply	*12Vdc 400ma*

Monitors

Monitor	***17"***	***18"***	***19" B/W***	***19"Color***
	Standard for unit with monitor aboard	Standard for camera $1K^2$, optional for camera $0,5K^2$	Standard per camera $0,5K^2$, opzional for camera $1K^2$.	Standard for camera $0,5K^2$, optional for camera $1K^2$.
Model	color base LCD 17" TFT	monochromatic LCD 18.1" TFT	monochromatic LCD 19" TFT B/N	color base LCD 19" TFT
Display angle	180°	170°	178°	178°
Contrast Ratio	1000:1	400:1 typical	700:1	800:1
Resolution	1280 x 1024	1280 x 1024	1280 x 1024	1280 x 1024
Pixel dimensions	0,264 x 0,264 mm	0,280 x 0,280mm	0,294 x 0,294 mm	0,294 x 0,294 mm
Grays scale	256 x 3 =768 levels	256 x 3 = 768 levels	256 x 3 = 768 levels	256 x 3 = 768 levels / 16,7 Mil colors
Brightness Max. luminance	350cd/m^2	750 cd/m^2 typical	800 cd/m^2 typical	250 cd/m^2 typical
Aspect Ratio	4:3	4:3	4:3	4:3
Response time	25ms	40ms	18ms	18ms
Video Standard	CCIR 625/50Hz EIA 525/60 1049/60 625/100Hz 1023/60 525/120	625 lines / 100Hz 4:3 interlaced 1249 lines / 50Hz 4:3 interlaced 1249 lines/60Hz 1:1 interlaced	VGA / DVI	VGA / DVI
Connectors	Nr.2 Connectors BNC 75ohm	Connector BNC 75ohm VGA connector S-Video connector RCA connector	D-Sub 15p. HD DVI-D BNC 75ohm per video compositi (B/N)	D-Sub 15p. HD; DVI-D; BNC 75ohm per video compositi.
Brightness / Contrast	Dedicate knobs	OSD menu	Control push-buttons	Control push-buttons
Power supply	115-230Vac, 60/50Hz	100-240Vac, 60/50Hz	100-240Vac, 60/50Hz	100-240Vac, 60/50Hz
Absorption	55W	60W	60W	42W
Weight	4kg (8,82 lb)	9,2kg (20,28 lb)	9,8kg (21,61 lb)	9,8kg (21,61 lb)
Mounting interface	VESA 100x100	VESA 100x100	VESA 100x100	VESA 100x100

5.7. Digital image processor

TV chain and Monitor with CCD 0,5K x 0,5 K

Features	***SBFM 76***	***SBFM 78/330***	***SBFM 78/2700***
Model	SBFM76	SBFM 78/330	SBFM 78/2700
Images number	L.I.H. Only Ram image	L.I.H. +330 (non volatile images)	L.I.H. + 2700 (non volatile images)
Image format	768x576x12 bits 50Hz 256 gray level	768x576x12 bit 50Hz 256 grey levels	768x576x12 bit 50Hz 256 grey levels
A/D Converter	8 bits	10 bit	10 bit
D/A Converter	8 bits	8 bit	8 bit
Sampling frequency	15 MHZ	15 MHZ	15 MHZ
Monitors number	1	2	2
Recursive Filter, noises reduction, OFF,2,4,8,16	YES 0,2,4,8,16	YES 0,2,4,8,16	YES 0,2,4,8,16
Digital rotation in real time	YES	YES	YES
Vertical image Inversion	YES, in combination with the rotation	YES, in combination with the rotation	YES, in combination with the rotation
Horizontal image inversion	YES	YES	YES
Grey scale Inversion	NO	YES	YES
Frame rate fps acquisition	Single store image	Single store image	Single store image
Image edge (EDGE)	YES	YES	YES
Patient data editing	NO	YES	YES
Video input	Standard CCIR 1 Vpp composite video signal 75 Ohm termination	Composite Video signal standard CCIR 1Vpp end 75 Ohm	Composite Video signal standard CCIR 1Vpp end 75 Ohm
Video output	BNC, Standard CCIR 1 Vpp composite video signal 75 Ohm termination	BNC, Composite Video signal standard CCIR 1Vpp end 75 Ohm	BNC, Composite Video signal standard CCIR 1Vpp end 75 Ohm
Power supply	20V to 36V dc	10Vdc ÷ 36Vdc	10Vdc ÷ 36Vdc
Dimensions	BOX (26x10,2x6,5)	BOX (26x10,2x6,5)	BOX (26x10,2x6,5)
Weight		....	...

Features	***DIP3000 A***
Model	DIP 3000 A
Number of images	L.I.H.+192 image buffer ram
Number of images in Hard Disk	About 40.000
Video signal	CCIR625/50, EIA 525/60, 1Vpp 75 Ohm
Image format working memory	576x576x12bit
Image format	576x576x8bit
A/D converter	10 bit
D/A converter	8 bit
Sampling rate	15 MHZ
Number of monitors	2
Flicker free	YES
Smart Filter, motion detector algorithms	YES
Virtual shutter	YES
Frame acquisition rate	YES, 1,3,6 fps
Recursive Filter, Noise reduction, OFF,2,4,8,16	YES 2,4,8,16
Left and Right image inversion	YES
Real time Digital rotation without X-Ray on memory	YES
Cine loop review	YES
Programmable frame rate acquisition	Yes, 1, 3, 6 fps
Zoom	YES, by 2
Overview	YES, 4/16 images
Contrast enhancement	YES
Edge enhancement Smooth, Normal, Sharp in real time	YES
Digital adjustment for contrast/brightness	YES
Positive/negative image display	YES
Text editing	YES
Overlay note	YES
Directory patients memory	YES
Max Opac.	YES
Road-mapping, capability for catheter Placement	YES
Real time Subtraction (DSA)	YES
Shifting Pixel	YES
Land Marking	YES
Connection with Dicom	YES, optional
Infrared Remote control	Optional

TV chain and Monitor with CCD 1K²

Features	***HRC 1000 type***
Images acquirement	1024 x 1024 x 16 bit
Images storage	1024 x 1024 x 10 bit up to 256 frames (option).
D/A converter	8 bits
Video input	Digital LVDS type 10 bits
Video output	2x 1249/1049 lines 50/60Hz interlaced 1x 625/525 lines 50/60Hz interlaced
Processing in real time	
Images number	L.I.H Last Image Hold + 256 images, output for 2 monitors
Images acquirement rates	Single image storage up to 256 images in ram or 50.000 images on hard disk (dicom).
Gamma correction	Yes, digital
Recursive filter / smart	Yes
Digital image rotation LIH	Yes
Edge enh 3x3	Yes
Dynamic range	1:2 1:3 1:4 1:5
Post Processing	
Grey scale inversion	Yes
Brightness and contrast	Yes
Overview, Windowing	Yes 4-9-16 images, 1+5 or 1+7 images
H/V inversion	Yes
Electronic zoom	Yes
Step rotation 90°	Yes
Continuous fluoroscopy	Yes
LIH	Yes
Pulsed fluoroscopy	Yes
Snapshot	Yes
LIH Autostore	Yes
LIH marker	Yes
Image numeration	Yes
Overview 4/9/16 images	Yes
Patients file	Yes
Images subtraction	Yes
Electronic diaphragms	Yes
Measures	
Distances calculation	Yes
Angles	Yes
Dicom Options	
	Dicom VERIFY (SCU/SCP) Dicom STORAGE (SCU) Dicom WORK LIST (SCU) Dicom PRINT (SCU) Dicom CDR/DVD Dicom QUERY/RETRIEVE (SCU)

Features	***HRP 2000***
Acquirement	
Images acquirement	From digital CCD 1024x1024 up to 12 bits Pulsed at high dose up to 12 images/second 1024x1024x12bit Fluoroscopy 25 images/second 1024x1024x8bit Fluoroscopy with recursive filter and movement holding Linear integration up to 16 images in pulsed acquirement
Images storage	1024 x 1024 x 12 bit
Images storage *on H.D*	SCSI type 36 Gbyte, 36.000 images with 1kx1k 8 bit 18.000 images with 1kx1k 12bit 144.000 images with 512 x512x8 bit
Video input	Digital, LVDS type 10 bits
Video output	D/A converter 10 bit, VGA 1280x1024 60Hz, interlaced 325 lines 50Hz only for printer.
Electronic rotation at 1° steps	Yes
Horizontal and vertical inversion	Yes
Grey scale inversion	Yes
Brightness and contrast	Yes
Max. opacity fluoroscopy acquirement	Yes
Subtraction in real time with manual/automatic mask	Yes
Programmed acquirement sequences	Yes, 3, 6, 12, 25 fps
Post Processing	
Image horizontal and vertical inversion	Yes
Brightness and contrast	Yes
Grey scale inversion	Yes
Edges enh	Yes
Cineloop	Yes
Electronic collimator (rectangular and circular)	Yes
Shifting pixels	Yes
Electronic zoom factor from 1,2 to 3	Yes
Electronic lens factor from 1,2 to 3	Yes
Images sum for noise reduction	Yes
Images composition for research of the max. contrast liquid concentration	Yes
Land marking	Yes
Overview 4-9-16 images	Yes
Image subtraction	Yes
Measures	
Distances calculation	Yes
Angles	Yes
Stenosis	Yes
Text overwriting	Yes
Data transmission towards PACS	
Interface for network Ethernet TCP/IP	Yes
Adapter of Wireless network 802.11 a/g/n	Optional
Options	
Infrared remote control	Yes
Dicom options	
	Dicom VERIFY (SCU/SCP) Dicom STORAGE (SCU) Dicom WORK LIST (SCU) Dicom PRINT (SCU) Dicom CDR/DVD Dicom QUERY/RETRIEVE (SCU) Dicom MPPS (CPU) Dicom STORAGE COMMITMENT (SCU)

DICOM2, DICOM3 Digital Imaging and Communications in Medicine (Option)

Description	***Data***
Network connection features:	ESIDIC2, ESIDIC3
Speed	Ethernet autosense 10/100 M bit/s
Protocol	TCP/IP
IP address	Personalizable in 4 byte
IP mask	Personalizable in 4 byte
Dicom connection features, Functions performed:	
Dicom VERIFY (scu/scp)	Supported
Dicom STORAGE (SCU)	Supported
Dicom WORKLIST (SCU)	Supported
Dicom PRINT (SCU)	Supported
Dicom CDR/DVD (media Interchange)	Supported
Dicom MPPS (SCU)	Not available
Dicom STORAGE COMMITMENT (SCU)	Not available
Dicom QUERY/RETRIEVE (SCU)	Not available for ESIDIC 2. Available for ESIDIC 3.
Dicom port address	Settable
Video Output on live LCD monitor High resolution	1249/50 Hz, 1049 60 Hz
Video output	VGA, 1280/1024 60 Hz
Hard disk	80 GB or more

DICOM Terminology

Terminology	***Description***
Dicom VERIFY (SCU/SCP)	It allows the connection check, in both ways, with Dicom units present on the network.
Dicom STORAGE (SCU)	It allows to send the images to a Dicom server for filing.
Dicom WORKLIST (SCU)	It queries and receives from a Dicom server the patients list to be examined on the acquirement system.
Dicom PRINT (SCU)	It sends to Dicom printer the images to be printed in panoramic way and through film composer.
Dicom CDR/DVD (media Interchange)	It burn on Cd or DVD the patients images with the possibility to add a display program.
Dicom MPPS-Modality Performed Procedure Step (SCU)	It informs the server that the examination is in operation and then that it has been completed by sending the reference indication to the images and, if available, the total acquirement dose.
Dicom STORAGE COMMITMENT (SCU)	It asks and wait for the confirmation to the storage server that the images sent are saved in a safe way by allowing the cancellation of the acquirement unit from the file.
Dicom QUERY/RETRIEVE (SCU)	It queries and receives from a server the images of a patient data for consultation.
SCU (SERVICE CLASS UNIT)*, unit that asks a Dicom service to a unit* ***SCP (SERVICE CLASS PROVIDER)*** *that is able to supply such service.*	

5.8. Accessories

Description	Standard	Optional
X-ray handswitch with extensible cable	•	
Fluoroscopy control by triple footswitch	•	
Cassette-holder for radiography on cassette 24x30cm		•
Cassette-holder for radiography on cassette 18x24cm		•
Cassette-holder for radiography on cassette 10x12inch		•
Sterile drapes set		•
Thermal dry film printer Sony UP 970 / UP 990 or equivalent		•
Medical Image Capture Device MediCap USB200		•
USB Data: 512 MB, 350 Kb per image, about 1450 image		•
USB Data: 2 GB, 350 Kb per image, about 5700 image		•
DVD Recorder Sony DVO 1000 MD. Automatic start- stop with DIP3000		•
DVD Recorder for Fluoro acquisition, Only manual Star Stop		•
Dicom Utility ESIDIC2 (only for DIP3000 memory)		•
Dicom Utility ESIDIC3 (only for HRC memory)		•
Laser Targeting device (only on I.I. tube)		•
Dose meter with ionization chamber (DAP) Diamentor CM-T		•
Printer for dose meter S Sprint s (on unit)		•
Collimator with iris and parallel shutter		•
Equipotential node cable lg.300		•
External interlocks kit		•
Movement handles on "C" arm		•
Movement handle on I.I. tube		•

Laser targeting device, for dose reduction (only on I.I. tube)

Description	*Data*
Wave length	635nm
Optical power of the laser diode	< 4 mW
Optical power of the collimated beam	< 3,5 mW
Divergence	6,67 mRad
Optical power on the operation plane	< 3 mW
Safety class	1A

Dose meter with ionizing chamber PTW, DIAMENTOR CM-T ((DAPMeter)

Description	*Data*
Measurement amplifier	
Measurement category	*Dose area product*
Measuring unit	μGy m^2
Digital resolution	0,01 μGy m^2
Measurement category	
Measurement category	*Dose area product rate*
Measuring unit	μGy m^2/s
Digital resolution	0,01 μGy m^2/s
Nominal useful range	
Dose rate range	0,10 to 400 mGy/sec
Max field dimension	ϕ 6 cm
Min field dimension	ϕ 0,6 cm
Dose area product range rate	0,01 to 4500 μGy m^2/s
Tube voltage	40 to 120 kV
Chamber:	Type TA34037
Dimension of chamber field	ϕ 7,2 cm
Max energy dependence	$\pm$ 8% according to IEC60580, Table 6
Hardening equivalent value	< 0,3 mmAl / 70 kV according to IEC60522/1999

Thermal Dose Meter Printer Custom S print s type

Printing method	Thermal line printing
Resolution	203 dpi
Printing speed	>50mm/sec (it depends on the printing typology and the environment temperature)
Paper width (mm	58mm
Roll dimensions (mm)	57.5 ±1
Print area	48mm
Interface	RS-232
Power Supply	18±24VDC / 0,6A
Power consumption (print)	925mA
Operating Temperature *Storage*	0±50°C, -20±70°C, without paper roll
Humidity *Operating Storage*	10±85%, there must be no condensation 10±90%, there must be no condensation, without paper roll
Dimensions (WxDxH)	146 x 88 x 65mm
Weight	370gr (without paper roll)
Safety	EN60950+A1+A2+A3+A4

Thermal printer Sony UP970CE or UP990CE

Description	***Data***
Print method	Thermal printer with multi image picture (UP 960 only 2 images) Sublimation print, not available
Thermal head	1280 elements
Grey levels	256 levels
Sheet format	Amplitude from 210 mm
Print dimensions UP990CE	Standard mode CCIR 187 x 138 mm ; EIA 187 x 140 mm
	Side mode CCIR 186 x 249 mm ; EIA 188 x 249 mm
Print dimensions UP970CE	Standard mode CCIR 190 x 142 mm ; EIA 190 x 144 mm
	Side mode CCIR 181 x 243 mm ; EIA 184 x 243 mm
Printer memory	UP960CE 2048 x 1024 x 8 bit; UP980CE 2048 x 2048 x 8 bit:
Printer time	Standard CCIR about 12 sec.; Standard EIA about 10 sec.
Inputs to the printer	CCIR or EIA videocomposed BNC 1.0 Vpp, 75 ohm high imped
Output from printer	CCIR or EIA videocomposed BNC 1.0 Vpp, 75 ohm high imped
Power supply	120 ÷ 240V 50 / 60 Hz
Size	316L x 132H x 305D mm
Weight	8 Kg
Paper	Thermal paper, dry blue film only for UP 980
Accessories	Remote control

Sony DVD Recorder DVO 1000MD

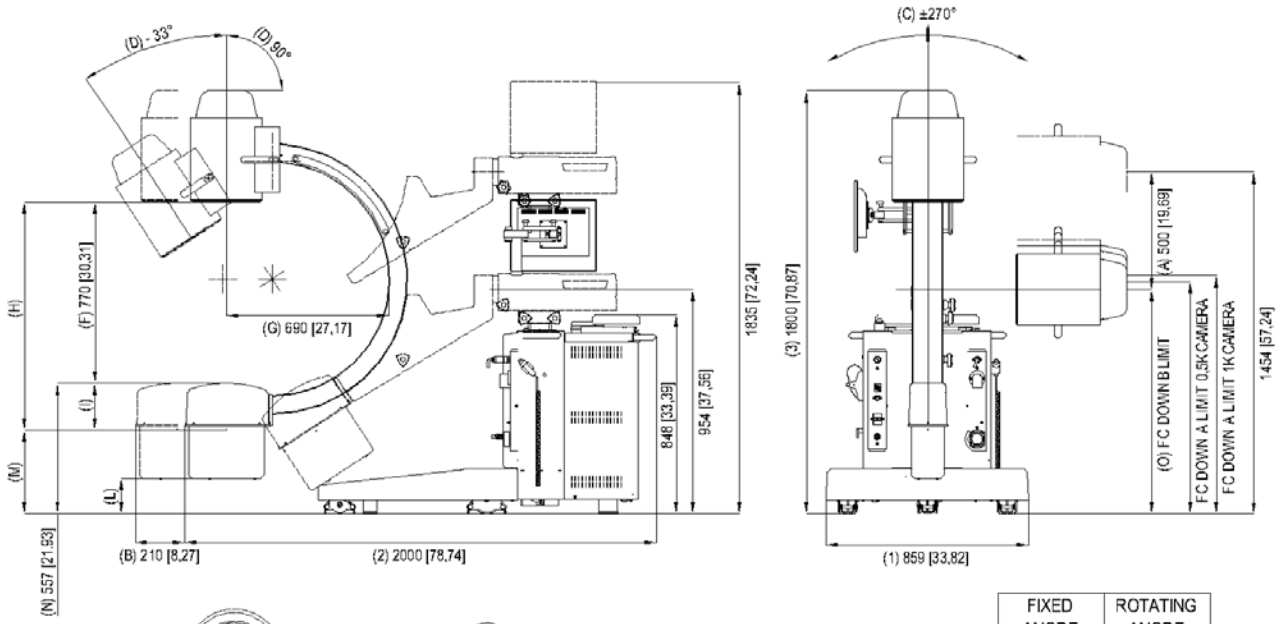
Description	***Data***
General data:	
Recording System	DVD recording, NTSC/PAL, Switchable
Recording Format	Video: MPEG-2 compression Audio: Dolby Digital Format
Recordable media	DVD+RW (2,4x and 4x speed)
Recording time	HQ mode: 60 minutes
SP mode	120 minutes
LP mode	180 minutes
Medical Standards	EN60601-1, EN60601-1-2, UL60601-1,CSAC22.2 N° 60601-1
Power Requirements	From 100 to 240 Vac 50/60 Hz
Power Consumption	35 W
Operating temperature	+5° to +40° C
Storage temperature	-20° to +60° C
Operating Humidity	From 20 to 80 %
Size	212 x 128,5 x 382 cm
Mass	6 Kg
Input / Output	
Analog Composite Input	BNCx2, with loop-through, unbalanced 1.0 Vpp 75 Ohm
S-Video Input	4 pin DIN x2, with loop- through Y: 1Vpp, 75 Ohm unbalanced C: 0,286 Vpp (NTSC)/ 0,3 Vpp (PAL), 75 Ohm, unbalanced
Analog Composite Output	BNC x1, 1±0,2 Vpp, 75 Ohm, unbalanced
S Video Output	4 pin DIN x1 Y: 1Vpp, 75 Ohm unbalanced C: 0,286 Vpp (NTSC)/ 0,3 Vpp (PAL), 75 Ohm, unbalanced
Analog Audio Input	RCA Pin x2 /L/R), 2 Vrms /full bit), input impedance 47 kOhm
Analog Audio Output	RCA Pin x2 /L/R), 2 Vrms /full bit), load impedance 47 kOhm
Monitor Audio Output	Monitor RCA Pin x1 /L/R), 2 Vrms /full bit), load impedance 47 kOhm
ILINK (DV IN)	ILINK 6-pin x1 IEEE1394
Remote Control	RS-232C x1 D-sub 9-pin USB 2.2 x1 (Full Speed) Remote 2 x1, stereo mini jack for connection with optional FS-20 foot switch

Medical Image Capture Device MediCap USB200

Description	***Data***
Model	MediCap USB200. Digital medical Image capture device. Saves digital images and video sources to a USB flash drive or USB hard drive. Equipped with USB Data: 2GB, 350 Kb per image, about 5700 image
Case	Rugged metal case with high-impact plastic faceplate
Buttons	Sealed membrane, fluid resistant
Video	PAL / NTSC (switch selectable) S-video or composite BNC connections for both input and output
Foot Switch	Hands-free capture. Standard 3.5 mini jack
Mechanical	Size: 240 x 200 x 63mm / 9.5 x 9.7 x 2.5” Weight: 1.7 Kg / 3lb
Environmental	Storage: -40° to +85° C - Operating: -20°n to +40° C
Power	100/240Vac 50-60Hz 20W 3-prong AC jack
Media	USB flash drives (MediCapture brand recommended) or external USB hard drive
Image Formats	DICOM, JPEG, TIFF, PNG
Video Formats	MPEG2 PS, DVD-quality. Quality Levels: Low (DVD-): 352 x 240 pixels, 1.5 Mbps Variable Bit Rate (VBR) Normal (DVD): NTSC: 720 x 480 pixels, 3.5 Mbps VBR PAL: 720 x 576 pixels, 3.5 Mbps VBR High (DVD+): NTSC: 720 x 480 pixels, 8 Mbps VBR PAL: 720 x 576 pixels, 8 Mbps VBR
Audio format	MPEG1 L2, 2 channels, 16 bits/channel, 48 kHz sampling 256 kbps bitrate
Image Size	1024 x 768 pixels, 800 x 600 pixels, 640 x 480 pixels
Certifications	IEC, UL, CSA, FCC

6. MECHANICAL DATA

6.1. C-arm unit dimensions with I.I. 9”



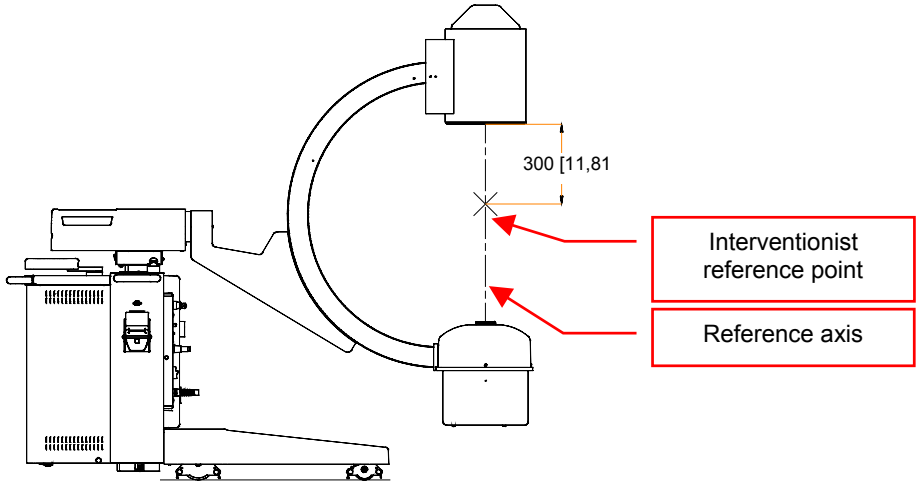
	FIXED ANODE	ROTATING ANODE
(H)	988 [38,90]	970 [38,19]
(I)	218 [8,58]	200 [7,87]
(L)	172 [6,77]	152 [5,98]
(M)	339 [13,35]	357 [14,06]

Measuring units of the dimensions: mm +/-2 [inch +/-0,08].

	FC UP	FC DOWN	
		A LIMIT	(O) B LIMIT
0,5K CAMERA	1454 [57,24]	989 [38,83]	954 [37,54]
1K CAMERA		1014 [39,92]	

Measuring units of the dimensions: mm +/-5 [inch +/-0,19].

6.2. Axis and interventionist reference point

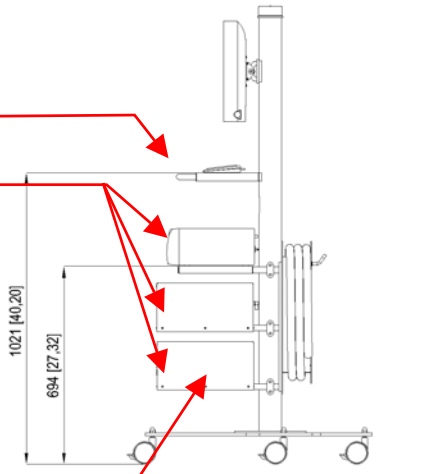


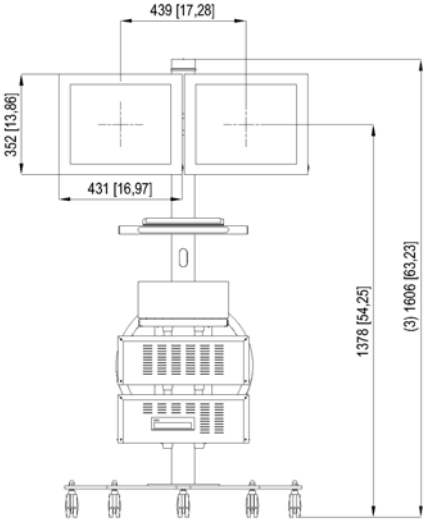
6.3. "Base Trolley" monitor trolley dimensions

max. admissible weights on the single shelves:

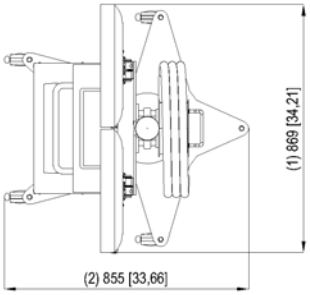
2 kg.

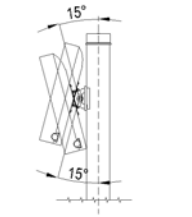
10 kg.





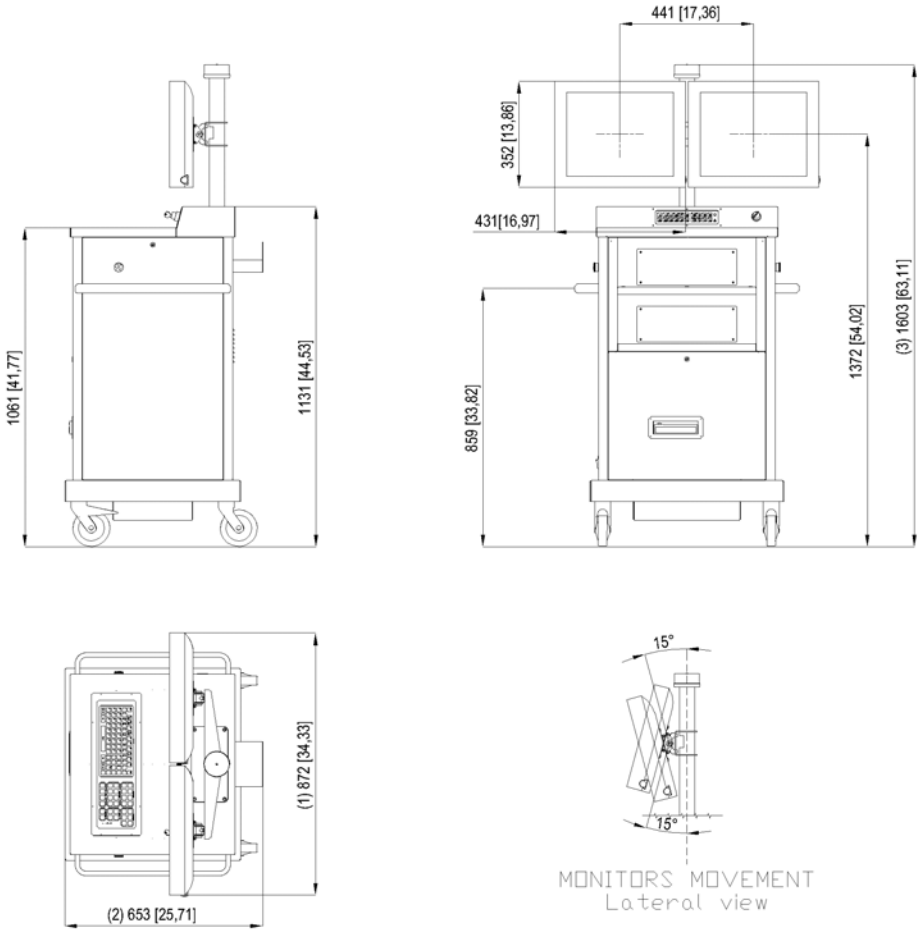
In the version "Low Profile Base Trolley" for systems 0,5K^2, the two lower shelves are not available.



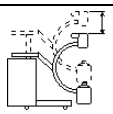
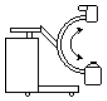
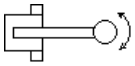
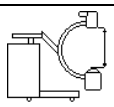
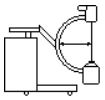


MONITORS MOVEMENT
Lateral view

6.4. Dimensions of "High Configuration" monitor trolley



6.5. Mechanical data, dimensions and weights

<table>
<tr><th>Description</th><th colspan="2">C-arm unit</th><th colspan="2">“Base Monitor Trolley”</th><th>“High Configuration” Monitor Trolley</th></tr>
<tr><td rowspan="2">Weight</td><td>340 kg
749,57 lb</td><td>(unit with fixed anode)</td><td rowspan="2">“Low Profile”
67kg
147,71 lb</td><td rowspan="2">“High Profile”
97 kg
213,85 lb</td><td rowspan="2">150Kg
330,69 lb</td></tr>
<tr><td>360kg
793,66 lb</td><td>(unit with rotating anode)</td></tr>
<tr><td>(1) Width</td><td colspan="2">859 mm (33,82 in)</td><td>869 mm
34,21 in</td><td>869 mm
34,21 in</td><td>872 mm
34,33 in</td></tr>
<tr><td>(2) Depth in movement position</td><td colspan="2">2000 mm (78,74 in)</td><td>855 mm
33,66 in</td><td>855 mm
33,66 in</td><td>653 mm
25,71 in</td></tr>
<tr><td>(3) Height in movement position</td><td colspan="2">1800 mm (70,87 in)
(camera 1k)
1780 mm (70,08 in)
(camera 0,5k)</td><td>1606 mm
63,23 in</td><td>1606 mm
63,23 in</td><td>1603 mm
63,11 in</td></tr>
<tr><td colspan="3">(A) Vertical motion  </td><td colspan="3">Total travel 500 mm (19,69 in) , motorized in 60 sec</td></tr>
<tr><td colspan="3">(B) Horizontal motion </td><td colspan="3">Manual, 210 mm (8,27 in)</td></tr>
<tr><td colspan="3">(C) C-arm rotation around the horizontal axis </td><td colspan="3">Manual, ±270°</td></tr>
<tr><td colspan="3">(D) Orbital rotation  </td><td colspan="3">Manual, 123° (+90° ÷ - 33°)</td></tr>
<tr><td colspan="3">(E) C-arm group overview  </td><td colspan="3">Manual, ±12,5°</td></tr>
<tr><td colspan="3">(F) Useful space  </td><td colspan="3">770 mm (30,31 in)</td></tr>
<tr><td colspan="3">(G) C-arm depth  </td><td colspan="3">690 mm (27,17 in)</td></tr>
<tr><td colspan="3">(H) S.I.D.</td><td colspan="3">971 mm (38,23 in) Rotating Anode
988 mm (38,90 in) Fixed Anode</td></tr>
<tr><td colspan="3">(I) Focus-Skin Distance</td><td colspan="3">200 mm (7,87 in) Rotating Anode
218 mm (8,58 in) Fixed Anode</td></tr>
<tr><td colspan="3">(L) Minimum distance from the floor</td><td colspan="3">152 mm (5,98 in) Rotating Anode
172 mm (6,77 in) Fixed Anode</td></tr>
<tr><td colspan="3">(M) Distance Floor - Focus</td><td colspan="3">357 mm (14,06 in) Rotating Anode
339 mm (13,35 in) Fixed Anode</td></tr>
<tr><td colspan="3">(N) Distance Floor - Skin</td><td colspan="3">557 mm (21,93 in)</td></tr>
<tr><td colspan="3">(O) Min. distance between I.I. center – floor in oblique projection</td><td colspan="3">954 mm (37,56 in)</td></tr>
<tr><td colspan="3">Unit movement</td><td colspan="3">C-arm unit:
Rear driving wheels with manual control by the operator, front castor. Manual parking brake.
Monitor trolley:
Front and rear castors. Brake on the front wheels</td></tr>
<tr><td rowspan="3">Wheels Diameter</td><td colspan="2">Unit</td><td colspan="3">Rear 125 x 40 mm (4,92 x 1,57 in)
Front 80 x 30 mm (3,15 x 1,18 in)</td></tr>
<tr><td rowspan="2">Trolley</td><td>Base Trolley</td><td colspan="2">80 x 35 mm (nr.5)
(3,15 x 1,38 in)</td></tr>
<tr><td>High Configuration Trolley</td><td colspan="2">125 x 30 mm (nr.4)
(4,92 x 1,18 in)</td></tr>
<tr><td colspan="3">Protection against the cables squashing</td><td colspan="3">Core hitch on all the C-arm unit wheels.</td></tr>
</table>

The measures are referred to the figure at page 73 (§6.1 -C-arm unit dimensions with I.I. 9”)

7. DOCUMENT STATUS

Rev.	*Date*	*Page/s*	*Modification description*
-	30/10/2007	-	Document approval
A	28/04/08	All	General document revision.
B	28/11/08	6, 10, 11, 21 25, 36, 38, 46, 47	Note addition on the unit versions. Note addition about the use of the overview movement handle. “Error of the field bus” alarm addition. Note addition about the unit-trolley connection cable insertion. Added automatic opening of the collimator diaphragms. Modified “User Setup” page. Added warning label.
C	06/04/09	14,18, 20, 44,47,48,54,5 7,58,60,61	Unification of the SNAPSHOT function wordings, added data of HiRad exposure time range, modification to the small focus from 0,6 to 0,5 on the OX/100-5 insert concerning the fixed anode monobloc and various corrections in the document. Updated description at point 3 of the “Operative Messages”
D	10/09/09	7, 44, 48, 52, 53. 68, 69, 70, 72	Introduced the new model of fixed anode monobloc and inverter. Added DICOM function, new Medicap USB200 model.
E	26/10/09	7, 43, 44, 47, 52, 54, 55, 61, 67, 68, 69, 70	Introduced the new model of rotating anode monobloc and inverter. Upgrading of manufacturer address and relative S/N labels Upgrading of data table HRP HRC DICOM and laser targeting device data.
F	26/05/10	12, 13, 30 34,35,37, 48,61	Insertion of the description of memory SBFM78 functions Introduction of the images export function on USB support Update of mAs data in “HiPower grapy”
G	13/07/10	37, 68	Introduction of the remote control and transfer of the Wireless images for the memory HRP2000.